JS 44 (Rev. 06/17) JP

CIVIL COVER SHEET

17-cv-2915

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

17 2915

I. (a) PLAINTIFFS

Pamela Winstrom

(b) County of Residence of First Listed Plaintiff Burbank, CA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
McCune Wright Arevalo LLP
Joseph G. Sauder; 555 Lancaster Ave, Berwyn, PA 19312

DEFENDANTS

Bayer Corp.; Bayer Healthcare, LLC; Bayer Essure, Inc.; and Bayer Healthcare Pharmaceuticals, Inc.

County of Residence of First Listed Defendant Pittsburgh, PA
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☒ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 196 Franchise				☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	☐ 462 Naturalization Application		☐ 893 Environmental Matters
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions	FEDERAL TAX SUITS	☐ 895 Freedom of Information Act
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 896 Arbitration
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 871 IRS—Third Party 26 USC 7609	☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty			☐ 950 Constitutionality of State Statutes
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	Other:			
	☐ 448 Education	☐ 540 Mandamus & Other			
		☐ 550 Civil Rights			
		☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC 1331; 28 USC 1367

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE See Attached DOCKET NUMBER

JUN 29 2017

DATE 06/29/2017

SIGNATURE OF ATTORNEY OF RECORD Joseph G. Sauder

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

JP

Address of Plaintiff: Burbank, CA 17 2915

Address of Defendant: 100 Bayer Road, Building 4, Pittsburgh, PA 15205

Place of Accident, Incident or Transaction: _____

(*Use Reverse Side For Additional Space*)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☒ No☐

Does this case involve multidistrict litigation possibilities? Attached Yes☒ No☐

RELATED CASE, IF ANY:

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☒ No☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☑ All other Federal Question Cases
    (Please specify) FDCA

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
   (Please specify) _____

ARBITRATION CERTIFICATION

(*Check Appropriate Category*)

I, Joseph G. Sauder, counsel of record do hereby certify:

☑ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: June 29, 2017 Joseph G. Sauder Attorney-at-Law 82467 Attorney I.D.# JUN 29 2017

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: June 29, 2017 Joseph G. Sauder Attorney-at-Law 82467 Attorney I.D.#

CIV. 609 (5/2012)

JP

I. (a) PLAINTIFFS [Continued]: 17 2915

SHERI ANDAMASARIS, WILLIAM ANDAMASARIS, APRIL AMISSION, JOE AMISSION, NICOLE MCELROY, TONYA PALMER, BRIDGET CHENAULT, CHRISTINA BAKER, LINDA HELLOMS, CHARLES HELLOMS, SHAQUEENA LOPER, CLARENCE LOPER, DARLISSA SADLER, SAUDIA JONES, TIFFANY DOWDY, TERRY PAGE, ANTHONY PAGE, JENNIFER DEALMEIDA, JARBAS DEALMEIDA, RACHEL KIRBY, EUGENE KIRBY, MEGAN BERRYHILL, NADINE MEAL, ERIKA SNODDY, ERIN KEMP, ROY KEMP, JULIE PUNG, JOYCE SNOTGRASS, SHYRA ISHAM

VIII. RELATED CASE(S) IF ANY:

JUDGE	DOCKET NUMBER
Hon. John R. Padova	16-1458 (Dunstan)
Hon. John R. Padova	16-1645 (Clark)
Hon. John R. Padova	16-1921 (Souto)
Hon. John R. Padova	16-2166 (B. Bailey)
Hon. John R. Padova	16-2154 (Campos)
Hon. John R. Padova	16-2717 (Morgan)
Hon. John R. Padova	16-3049 (Tulgetske)
Hon. John R. Padova	16-3409 (Abbey)
Hon. John R. Padova	16-3589 (Burgis)
Hon. John R. Padova	16-3710 (Donahue)
Hon. John R. Padova	16-3730 (Mantor)
Hon. John R. Padova	16-3731 (O'Donnell)
Hon. John R. Padova	16-3732 (Gross)
Hon. John R. Padova	16-3733 (Johnson)
Hon. John R. Padova	16-3766 (Summerlin)
Hon. John R. Padova	16-3767 (Rodvill)
Hon. John R. Padova	16-3768 (Bernal)
Hon. John R. Padova	16-3769 (Aponte)
Hon. John R. Padova	16-4081 (Bradford)
Hon. John R. Padova	14-7315
Hon. John R. Padova	14-7316
Hon. John R. Padova	14-7317
Hon. John R. Padova	14-7318
Hon. John R. Padova	15-384

JP

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

PAMELA WINSTROM, et al., : CIVIL ACTION

v. :

BAYER, CORP., et al. : NO. 17 2915

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

June 29, 2017	/s/ Joseph G. Sauder	Plaintiffs
Date	**Attorney-at-law**	**Attorney for**
(909) 557-1250	(909) 557-1275	jgs@mccunewright.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

JUN 29 2017

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PAMELA WINSTROM, SHERI ANDAMASARIS, WILLIAM ANDAMASARIS, APRIL AMISSION, JOE AMISSION, NICOLE MCELROY, TONYA PALMER, BRIDGET CHENAULT, CHRISTINA BAKER, LINDA HELLOMS, CHARLES HELLOMS, SHAQUEENA LOPER, CLARENCE LOPER, DARLISSA SADLER, SAUDIA JONES, TIFFANY DOWDY, TERRY PAGE, ANTHONY PAGE, JENNIFER DEALMEIDA, JARBAS DEALMEIDA, RACHEL KIRBY, EUGENE KIRBY, MEGAN BERRYHILL, NADINE MEAL, ERIKA SNODDY, ERIN KEMP, ROY KEMP, JULIE PUNG, JOYCE SNOTGRASS, SHYRA ISHAM, Plaintiffs, vs. BAYER, CORP.; BAYER HEALTHCARE, LLC; BAYER ESSURE, INC.; and BAYER HEALTHCARE PHARMACEUTICALS, INC., Defendants.	NO.: JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES

TABLE OF CONTENTS

Page

NOW COME Plaintiffs, PAMELA WINSTROM, SHERI ANDAMASARIS, APRIL AMISSION, NICOLE MCELROY, TONYA PALMER, BRIDGET CHENAULT, CHRISTINA BAKER, LINDA HELLOMS, SHAQUEENA LOPER, DARLISSA SADLER, SAUDIA JONES, TIFFANY DOWDY, TERRY PAGE, JENNIFER DEALMEIDA, RACHEL KIRBY, MEGAN BERRYHILL, NADINE MEAL, ERIKA SNODDY, ERIN KEMP, JULIE PUNG, JOYCE SNOTGRASS, SHYRA ISHAM, who, in filing this Complaint, seek judgment against Defendants BAYER CORP.; BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER ESSURE, INC.; and BAYER HEALTHCARE, LLC (hereinafter collectively referred to as "Defendants") for the personal injuries they sustained as a result of being prescribed, receiving, and subsequently using the defective and unreasonably dangerous permanent birth control device Essure®. At all times relevant hereto, Essure® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold by Defendants or Conceptus, Inc., which was acquired by Defendants on or about April 28, 2013.

I

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Pamela Winstrom is a citizen of Burbank, California.
2. Plaintiff Sheri Andmasaris is a citizen of Girard, Ohio.
3. Plaintiff William Andmasaris is a citizen of Girard, Ohio.
4. Plaintiff April Amission is a citizen of Forked River, New Jersey.
5. Plaintiff Joe Amission is a citizen of Forked River, New Jersey.
6. Plaintiff Nicole McElroy is a citizen of Fairfield, Iowa.
7. Plaintiff Tonya Palmer is a citizen of Clinton, Iowa.

8. Plaintiff Bridget Chenault is a citizen of Hillard, Ohio.

9. Plaintiff Christina Baker is a citizen of Keller, Texas.

10. Plaintiff Linda Helloms is a citizen of White Hall, Arkansas.

11. Plaintiff Charles Helloms is a citizen of White Hall, Arkansas.

12. Plaintiff Shaqueena Loper is a citizen of Forest, Mississippi.

13. Plaintiff Clarence Loper is a citizen of Forest, Mississippi.

14. Plaintiff Darlissha Sadler is a citizen of Conyers, Georgia.

15. Plaintiff Saudia Jones is a citizen of Newport News, Virginia.

16. Plaintiff Tiffany Dowdy is a citizen of Clarksville, Tennessee.

17. Plaintiff Terry Page is a citizen of Detroit, Michigan.

18. Plaintiff Anthony Page is a citizen of Detroit, Michigan.

19. Plaintiff Jennifer DeAlmeida is a citizen of Wilmington, North Carolina.

20. Plaintiff Jarbas DeAlmeida is a citizen of Wilmington, North Carolina.

21. Plaintiff Rachel Kirby is a citizen of North Ridgeville, Ohio.

22. Plaintiff Eugene Kirby is a citizen of North Ridgeville, Ohio.

23. Plaintiff Megan Berryhill is a citizen of Ardmore, Oklahoma.

24. Plaintiff Nadine Meal is a citizen of Roseville, Michigan.

25. Plaintiff Erika Snoddy is a citizen of Knoxville, Tennessee.

26. Plaintiff Erin Kemp is a citizen of Cincinnati, Ohio

27. Plaintiff Roy Kemp is a citizen of Cincinnati, Ohio

28. Plaintiff Julie Pung is a citizen of Lansing, Michigan.

29. Plaintiff Joyce Snotgrass is a citizen of Eudora, Kansas.

30. Plaintiff Mikesha Barnett is a citizen of Carrollton, Texas.

31. Plaintiff Shyra Isham is a citizen of Oklahoma City, Oklahoma.

32. BAYER CORP. is a for-profit corporation that was incorporated in the state of Indiana, with its principal place of business in the Commonwealth of Pennsylvania at 100 Bayer Road, Building 4, Pittsburgh, Pennsylvania 15205. As such, Defendant is authorized to do, and does business, through the Commonwealth of Pennsylvania.

33. BAYER CORP. is the parent corporation of BAYER HEALTHCARE, LLC, BAYER ESSURE, INC., and BAYER HEALTHCARE PHARMACEUTICALS, INC. (the "Bayer subsidiaries"). BAYER CORP. owns 100 percent of the Bayer subsidiaries.

34. At all times relevant herein, the BAYER subsidiaries are agents or apparent agents of BAYER CORP. As such, each Defendant acted as agents of the other Defendants and acted within the course and scope of the agency regarding the acts and omissions alleged. Additionally, Defendants together acted in concert and/or abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of enriching themselves and creating an injustice at the expense of Plaintiffs.

35. Further, the Bayer subsidiaries, individually and/or collectively, are "Alter Egos" of BAYER CORP. as, *inter alia*, they are wholly owned by BAYER CORP; share the same trademark; share management and officers; and, in other ways, were dominated by BAYER CORP.

36. Moreover, there exists and, at all times relevant herein, there existed a unity of interest in ownership among all Defendants such that individuality and separateness between and among them has concluded. Since Defendants are "Alter Egos" of one another and exert control over each other, adherence to the fiction of separate existence of these Defendants as entities distinct from one another will permit an abuse of the corporate privilege, sanction fraud, and

promote injustice. BAYER CORP. wholly ignored the separate status of the Bayer subsidiaries and so dominated and controlled its affairs that its separate entities were a sham.

37. Defendant BAYER HEALTHCARE, LLC, is a for-profit corporation incorporated in the state of Delaware. Defendant BAYER HEALTHCARE, LLC's headquarters are located at 100 Bayer Boulevard, Whippany, New Jersey. Defendant is authorized to and does business throughout the Commonwealth of Pennsylvania.

38. Defendant BAYER ESSURE, INC., is a for-profit corporation incorporated in the state of Delaware. Defendant BAYER ESSURE, INC.'s headquarters are located at 100 Bayer Boulevard, Pittsburgh, Pennsylvania. Defendant is authorized to and does business throughout the Commonwealth of Pennsylvania.

39. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC., is a for-profit corporation incorporated in the state of Delaware. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.'s headquarters are located at 100 Bayer Boulevard, Whippany, New Jersey. Defendant is authorized to and does business throughout the Commonwealth of Pennsylvania.

40. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because complete diversity in citizenship exists between the Plaintiffs and all Defendants, and the amount in controversy exceeds seventy-five thousand dollars ($75,000) exclusive of interest and costs.

41. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) and (3) because a substantial part of the events or omissions giving rise to the claim occurred in this district, and Defendants regularly transact substantial business in this district and are subject to personal jurisdiction in this district. Additionally, Defendants have advertised in this district and

have received substantial revenue and profits from their sales of Essure® devices in this district; therefore, a substantial part of the events and/or omissions giving rise to the claims occurred, in part, within this district.

42. This Court has personal jurisdiction over Defendants because they have conducted substantial business in this judicial district and, intentionally and purposefully, placed the Essure® devices into the stream of commerce within Pennsylvania and throughout the United States.

II

INTRODUCTION

43. This Complaint is brought by Plaintiffs who were implanted with a female birth control device known as "Essure." In short, the device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage. However, in reality, the device migrates from the tubes, perforates organs, breaks into pieces and/or corrodes, wreaking havoc on the female body.

44. As a result of (1) Defendants' negligence described *infra* and (2) Plaintiffs' reliance on Defendants' warranties and representations, Defendants' Essure devices migrated, fractured, punctured internal organs, and/or caused other serious injuries.

45. Essure had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, Essure became "adulterated" and "misbranded"due to (1) Defendants' failure to conform to the FDA requirements prescribed in the CPMA and (2) violations of federal statutes and regulations noted *infra.*

46. Pursuant to Defendants' CPMA (which reads: "Failure to comply with conditions

of approval invalidates this approval order"), the C.F.R., and Federal Food, Drug and Cosmetic Act ("FDCA"), the product is "adulterated" and "misbranded" and, thus, could not have been marketed or sold to Plaintiffs.

47. Specifically, Essure was adulterated and misbranded as Defendants (1) failed to meet regular reporting requirements; (2) failed to report known hazards to the FDA; and (3) failed to comply with federal laws regarding marketing and distribution as specifically described *infra.*

48. The fact that Defendants failed to comply with these conditions is not a mere allegation made by Plaintiffs. These failures to comply with both the CPMA and federal regulations are memorialized in several FDA findings, including Notices of Violations and Form 483s issued by the FDA.

49. As discussed in greater detail *infra*, Defendants were cited by the FDA and the Department of Health for:

a. failing to report and actively concealing eight (8) perforations which occurred as a result of Essure;

b. erroneously using non-conforming material in the manufacturing of Essure;

c. failing to use pre-sterile and post-sterile cages;

d. manufacturing Essure at an unlicensed facility; and

e. manufacturing Essure for three (3) years without a license to do so.

50. Defendants were also found, by the FDA, to be:

a. Not reporting … complaints in which their product migrated;

b. Not reporting to the FDA incidents of bowel perforation, Essure coils breaking into pieces and migrating out of the fallopian tubes.

c. Only disclosing 22 perforations while having knowledge of 144

perforations;

d. Not considering these complaints in their risk analysis for the design of Essure;

e. Failing to have a complete risk analysis for Essure;

f. Failing to analyze or identify existing and potential causes of non-confirming product and other quality problems;

g. Failing to track the non-conforming product;

h. Failing to follow procedures used to control products which did not conform to specifications;

i. Failing to have complete Design Failure Analysis;

j. Failing to document CAPA activities for a supplier corrective action;

k. Failing to disclose 16,047 complaints to the FDA as Medical Device Reports ("MDR"); and

l. Failing to provide the FDA with timely post-approval reports for its six months, one year, eighteen months, and two years report schedules.

51. Most egregiously, on May 30, 2013, the FDA uncovered an internal excel spreadsheet with 16,047 entries of complaints which were not properly reported to the FDA. Here, Defendants did not disclose to the FDA complaints where its product migrated outside of the fallopian tube. Defendants' excuse was that those complaints were not reported because the patients were "not at last contact experiencing pain….and were mere trivial damage that does not rise to the level of a serious injury." The FDA again warned Defendants for violations of the FDCA.

52. As a result, the "adulterated" and "misbranded" product, Essure, which was implanted in Plaintiffs, should never have been marketed or sold to Plaintiffs pursuant to federal law.

53. Lastly, Defendants concealed and altered the medical records of its own clinical

trial participants to reflect favorable data. Specifically, Defendants altered medical records to reflect less pain than what was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process. Subsequently, Defendants failed to disclose this and concealed it from Plaintiffs and their implanting physicians.

54. Plaintiffs' causes of action are all based on deviations from the requirements in the CPMA and/or violations of federal statutes and regulations.

55. Plaintiffs' causes of action are also based entirely on the express warranties, misrepresentations, and Defendants' deceptive conduct, which were relied upon by Plaintiffs prior to having the device implanted. Under Pennsylvania law, Plaintiffs' claims for breach of express warranties are not preempted by the Medical Device Act ("MDA").

56. In addition, Defendants failed to comply with the following express conditions and federal regulations:

a. "Within 10 days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

b. "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

c. Report Due Dates – six months, one year, eighteen months, and two-year reports.

d. A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

e. Effectiveness of Essure is established by annually reporting on the 745 women who participated in the clinical tests.

f. Successful bilateral placement of Essure is documented for newly trained physicians.

g. Warranties are truthful, accurate, and not misleading.

h. Warranties are consistent with applicable federal and state law.

57. These violations rendered the product "adulterated" and "misbranded" – precluding Defendants from marketing or selling Essure and, more importantly, endangered the lives of Plaintiffs and hundreds of thousands of women.

58. Defendants actively concealed these violations and never advised Plaintiffs of the same. Had Plaintiffs known that Defendants were concealing adverse reactions, not using conforming material approved by the FDA (and failing to track the nonconforming material), not using sterile cages, operating out of an unlicensed facility, and manufacturing medical devices without a license, they never would have had Essure implanted.

III

DESCRIPTION OF ESSURE AND HOW IT WORKS

59. Essure is a permanent form of female birth control (female sterilization). The device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage.

60. Essure consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. All components are intended for a single use.

61. The micro-inserts are comprised of two (2) metal coils which are placed in a woman's fallopian tubes via Defendants' disposable delivery system and under hysteroscopic guidance (camera).

62. The hysteroscopic equipment needed to place Essure was manufactured by a third

party, is not a part of Defendants' CPMA, and is not a part of Essure. However, because Plaintiffs' implanting physicians did not have such equipment, Defendants provided it so that it could sell Essure.

63. The coils are comprised of nickel, steel, nitinol, and PET fibers. In other words, the coils are metal-on-metal.

64. Defendants' disposable delivery system consists of a single handle which contains a delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians are allowed to visualize this complicated process through the hysteroscopic equipment provided by Defendants.

65. After placement of the coils in the fallopian tubes by Defendants' disposable delivery system, the micro-inserts expand upon release and are intended to anchor into the fallopian tubes. The PET fibers in the coil allegedly elicit tissue growth blocking off the fallopian tubes.

66. The coils are supposed to remain securely in place in the fallopian tubes for the life of the consumer and not migrate, break, or corrode.

67. Three months after implant, patients are to receive a "Confirmation" test to determine if the micro-inserts are in the correct location and that the tissue has created a complete occlusion. This is known as a hysterosalpingogram ("HSG Test" or "Confirmation Test").

68. Regardless of the Confirmation Test, Defendants warrant that Essure allows for visual confirmation of each inserts proper placement during the procedure.

69. Essure was designed, manufactured, and marketed to be used by the average

gynecologist as a “quick and easy” and “non-surgical” outpatient procedure to be done without anesthesia.

IV

EVOLUTION OF ESSURE

70. Essure was first designed and manufactured by Conceptus, Inc. (“Conceptus”).

71. Conceptus and Defendants merged on or about April 28, 2013.

72. For purposes of this lawsuit, Conceptus and Defendants are one in the same.

73. Essure, a Class III medical device, is now manufactured, sold, distributed, marketed, and promoted by Defendants.

74. Defendants trained physicians, including Plaintiffs’ implanting physicians, on how to implant Essure and use hysteroscopic equipment.

75. Prior to the merger between Conceptus and the Bayer defendants, Conceptus obtained CPMA for Essure.

76. By way of background, Premarket Approval (“PMA”) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. According to the FDA, Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

77. PMA is intended to be a stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA.

78. An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device if it complies with federal laws and is not "adulterated" or "misbranded".

79. FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission.

80. However, the PMA process for Essure was "expedited", and several trial candidates' medical records were altered to reflect favorable data.

81. According to the FDA, a Class III device that fails to meet CPMA requirements is considered to be adulterated under section 501(f) of the FDCA and cannot be marketed, distributed, or advertised under 21 C.F.R. 814.80.

82. Regarding the PMA, devices can either be "approved", "conditionally approved," or "not approved."

83. Essure was "conditionally approved". It had CPMA, not PMA, which is the "gold standard".

84. In the CPMA Order issued by the FDA, the FDA expressly stated, "Failure to comply with the conditions of approval invalidates this approval order[1]." The following were conditions of approval:

a. "Effectiveness of Essure is established by annually reporting on the 745 women who took part in clinical tests."

b. "Successful bilateral placement of Essure is documented for newly trained physicians."

[1] Note: The CPMA order does not read…failure to comply *may* invalidate the order.

c. "Within 10 days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

d. "Report to the FDA whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

e. Warranties are truthful, accurate, and not misleading.

f. Warranties are consistent with applicable federal and state law.

g. Conduct a post approval study in the United States to document the bilateral placement rate for newly trained physicians.

h. Include results from the annual reporting on the patients who took part in the Pivotal and Phase II clinical investigations in the labeling as these data become available.

i. Submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

j. Submit a PMA supplement whenever there are changes to the performance of the device.

V

REQUIREMENTS UNDER FEDERAL REGULATIONS

85. The CPMA also required Defendants to comply with the Medical Device Reporting regulations and post market requirements for Class III medical devices:

a. Report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device may have caused or contributed to serious injury;

b. Report to the FDA within thirty (30) days whenever they receive notice of serious injury;

c. Report to the FDA information suggesting that one of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, 21 CFR §§ 803.50 et seq.;

d. Monitor the product after pre-market approval and discover and report to

the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.;

e. Submit a PMA Supplement for any change in manufacturing site, 21 CFR §§ 814.39 et seq.;

f. Establish and maintain quality system requirements to ensure that quality requirements are met, 21 CFR § 820.20 et seq.;

g. Establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, 21 CFR §§ 820.30 et seq.;

h. Document all Corrective Action and Preventative Actions taken by the manufacturer to address non-conformance and other internal quality control issues, 21 CFR §§ 820.100 et seq.;

i. Establish internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq. and §§ 820.20 et seq.;

j. Establish Quality Management System (QMS) procedures to assess potential causes of non-conforming products and other quality problems, 21 CFR §§820.70 et seq. and 21 CFR §§ 27 820.90 et seq.;

k. Report on Post Approval Studies in a timely fashion, 21 CFR §§ 814.80;

l. Advertise the device accurately and truthfully, 21 CFR §§ 801 et seq.

86. Defendants were also, at all, times responsible for maintaining the labeling of Essure. Accordingly, Defendants had the ability to file a "Special PMA Supplement – Changes Being Effected" ("CBE") which allows Defendants to unilaterally update the labeling of Essure to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d). These changes include:

a. Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. Labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

d. Changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

87. Upon obtaining knowledge of these potential device failure modes, Defendants were required under the Essure CPMA, 21 CFR §§820.30 et seq., 21 CFR §§ 820.100 et seq., and the FDA Recognized Consensus Standard ISO 14971, to use this information to routinely update the risk analyses for the Essure device and take any and all Corrective Action and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues. Furthermore, Defendants were required to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects. 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq.

VI

FAILURES OF ESSURE

88. After obtaining the CPMA, Defendants became aware of potential quality and failure modes associated with Essure and failed to warn Plaintiffs and/or their implanting physicians. Defendants became aware that the following failures could occur with the device and lead to adverse consequences for the patient:

a. The stainless steel used in Essure can become un-passivated, which allows it to rust and degrade;

b. The nitinol could have a nickel rich oxide, which the body attacks;

c. The "no lead" solder could, in fact, have trace lead in it;

d. The Galvanic action between the metals used to manufacture Essure,

which causes the encapsulation of the product within the fallopian tubes, could be a continuous irritant to some patients;

e. The nitinol in the device can degrade due to High Nickel Ion release, increasing the toxicity of the product for patients;

f. Latent manufacturing defects, such as cracks, scratches, and other disruption of the smooth surface of the metal coil, may exist in the finished product, causing excess nickel to leach into the surrounding tissues after implantation;

g. Degradation products of polyethylene terephthalate (PET) used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues; and

h. The mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body.

VII

VIOLATIONS OF FEDERAL REQUIREMENTS

89. In June 2002, the FDA found the following objectionable conditions:

a. Design outputs were not completely identified.

b. Corrective and preventative action activities were not being documented, including implementation of corrective and preventative actions.

c. Procedures addressing verification of corrective and preventative actions were not implemented.

90. In July 2002, during an inspection of Defendants' facility, the FDA observed that adverse events were not captured in the data.

91. In July of 2002, the FDA found that:

a. Defendant "does not have an assurance/quality control unit".

92. In June 2003, the following observations were made by the FDA which resulted in the FDA issuing Form 483s:

a. Two lot history records showed rejected raw materials which was not

documented and, therefore, could not be tracked.

b. Procedures were not followed for the control of products that did not conform to specifications.

93. In December 2010, the FDA found that Defendants were "not reporting complaints of their product being seen radiographically in the patient's abdominal cavity" and "did not have a risk analysis of the coils being in the abdominal cavity".

94. Defendants failed to comply with several conditions, including:

a. Defendants failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteenth month and two year reports. All reports failed to meet the respective deadlines.

b. Defendants failed to document successful placement of Essure, concealing the failure rates.

c. Defendants failed to notice the FDA of several adverse reactions and actively concealed the same. Defendants failed to report eight (8) perforations, which occurred as a result of Essure, and was cited for the same by the FDA via Form 483.[2]

d. Defendants failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury, concealing the injuries. Again, Defendants failed to report eight (8) perforations which occurred as a result of Essure to the FDA as evidenced in Form 483.

e. As outlined *infra*, Defendants' warranties were not truthful or accurate, and were, in fact, misleading.

f. Defendants' warranties were not consistent with applicable federal and state law.

g. Defendants failed to notice the FDA of their internal Excel file containing 16,047 entries of complaints.

95. Defendants also were found to be:

[2] Form 483 is issued to firm management at the conclusion of inspections when an FDA investigator has observed any conditions that violate the FDCA rendering a device "adulterated".

a. Erroneously using non-conforming material in the manufacturing of Essure and not tracking where it went.

b. Failing to use pre-sterile and post-sterile cages.

c. Manufacturing Essure at an unlicensed facility.

d. Manufacturing Essure for three years without a license to do so.

e. Not reporting … complaints in which their product migrated.

f. Not considering these complaints in their risk analysis for the design of Essure.

g. Failing to document CAPA activities for a supplier corrective action.

96. Specifically, it was determined that:

a. On January 6, 2011, the FDA issued a violation to Defendants for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes. Defendants were issued these violations for dates of incidents 5/11/10, 9/1/10, 10/1/10, 10/5/10, 10/26/10, 11/3/10, 11/5/10, and 11/16/10.

b. Defendants had notice of 168 perforations, but only disclosed 22 to the FDA.

c. On January 6, 2011, Defendants were cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure did not include, as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

d. On January 6, 2011, Defendants were cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendants' engineers learned of this, and it was not documented.

e. On July 7, 2003, Defendants were cited for not analyzing and identifying existing and potential causes of non-conforming product and other quality

problems. Specifically, two lot history records showed rejected raw material was not documented on a quality assurance form which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).

f. On July 7, 2003, Defendants were cited for not following procedures used to control products which did not conform to specifications.

97. In response, Defendants admitted that "the device may have caused or contributed to a death or serious injury, and an MDR Report is required to be submitted to FDA".

98. In addition, Defendants' failure to timely file MDRs and to report to the FDA the complaints that were not addressed by the device's labeling and/or complaints that were occurring with an unexpected increase in severity and frequency, which it knew of from the more than 32,000 complaints it received, violated the CPMA, FDA post-marketing regulations and parallel state law.

99. Moreover, Defendants did not provide the requisite training to the implanting physicians prior to selling it to the same.

VIII

FDA HEARINGS AND RESULTING ACTION

100. Defendants' conduct not only violated its federal regulatory duties and its duties under state law, but also caused a massive failure of information that has to be present in the medical and scientific community to protect a patient's interest. Because Defendants failed to timely, completely, or accurately report their knowledge of the risks and complications associated with the Essure device, the public's knowledge of the risks associated with Essure were seriously hampered and delayed. This endangered patient safety, including Plaintiffs' safety.

101. As the FDA continued to force Defendants to provide additional information

known to them that had been withheld, more information belatedly was made known to the medical community, including information concerning the frequency, severity, and permanence of complications associated with the prescription and implementation of Essure.

102. This belated and untimely release of relevant and important information lead to an increasing number of adverse events being reported to the FDA about Essure from patients and physicians. Because of these complaints, the FDA convened a public hearing concerning the safety and efficacy of Essure. At that hearing, Defendants continued to misrepresent the safety and efficacy of Essure. For example, Defendants stated that:

a. The efficacy rates for Essure are 99.6%; in reality, studies show that the chances of becoming pregnant with Essure are higher than with tubal ligations and higher than the rates reported by Bayer to the FDA at the public hearing;

b. Defendants testified that skin patch testing is not a reliable predictor of clinically significant reactions to nickel-containing implantable devices, including Essure. Despite this, Bayer told physicians and patients that a nickel sensitivity test was sufficient to determine whether a patient was a suitable candidate for an Essure device;

c. Defendants testified that "[a]s an alternative to Essure, laparoscopic tubal ligation is a safe and effective method of permanent birth control". In reality, studies show that the chances of becoming pregnant with Essure are higher than with tubal ligations, and Essure patients are much more likely to require additional surgeries to correct complications associated with the sterilization procedure;

d. Defendants testified that most of the reports of adverse events to the FDA have come from consumers and not Defendants, which is unusual. In reality, Defendants failed to report thousands of complaints of adverse events that it had received.

103. On February 29, 2016, the FDA first publicly announced "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device. The FDA took the following actions:

a. The FDA is requiring a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions". The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device."

b. The FDA is requiring Defendants to implement a Patient Decision Checklist "to help to ensure women receive and understand information regarding the benefits and risks" of Essure. The FDA's draft Patient Decision Checklist is a five-page document that the physician will discuss with each patient interested in using the device. The patient must initial after each topic of discussion, and both the physician and patient must sign the document. The topics for discussion include, *inter alia*, the risks for "adverse events including persistent pain, device puncture of the uterus and/or fallopian tubes ('perforation'), or movement of the device into the abdomen or pelvis ('intra-peritoneal migration')"; "allergy or hypersensitivity reactions"; symptoms such as changes in the skin (rash, itching), "chest pain, palpitations, breathing difficulties or wheezing, and intestinal discomfort such as nausea, diarrhea, and vomiting"; "joint or muscle pain, muscle weakness, excessive fatigue, hair loss, weight changes, and mood changes"; the fact that "there is no reliable test to predict ahead of time who may develop a reaction to the device"; the possibility that the Essure device "can move after placement," possibly becoming ineffective at preventing pregnancy or leading to "serious adverse events such as bleeding or bowel damage, which may require surgery to address"; and the fact that if the Essure device has to be removed after placement, it will require surgery to remove and, possibly, a hysterectomy.

c. The FDA has also ordered Bayer "to conduct a new post-market surveillance study designed to provide important information about the risks of the device in a real-world environment". The study must provide data on "the risks associated with Essure® and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure® device. The study will also evaluate how much these complications affect a patient's quality of life. . . .The FDA will use the results of this study to determine what, if any, further actions related to Essure® are needed to protect public health."

104. Unfortunately, this new warning, labeling, and patient decision checklist came too

late to warn Plaintiffs of the true risks of Essure. Had Defendants complied with their federal regulatory duties and their duties under state law by reporting the known risks and complications in a timely fashion, Plaintiffs and their physicians would have had this relevant, critical information available to them prior to the implant of Essure. At all relevant times, Defendants' Essure product was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants. Moreover, Defendants' misrepresentations regarding Essure discussed *infra*, in effect, over-promoted Essure and nullified otherwise adequate warnings.

105. Lastly, although Essure appears at first glance to be a "medical device", Defendants actually categorize it as a "drug".

106. In short, Essure is considered an "adulterated" and "misbranded" product that could not have been marketed or sold to Plaintiffs per the FDA and federal law, and all of Plaintiffs' claims center around violations of the CPMA requirements and/or federal regulations and statutes.

IX

DEFENDANTS' TRAINING AND DISTRIBUTION PLAN

107. Defendants (1) failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians; (2) provided specialized hysteroscopic equipment to the implanting physicians who were not qualified or competent to use the same; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing on and monopolizing the birth control market at the expense of Plaintiffs' safety and well-being.

108. Because Essure was the first device of its kind, the implanting physicians were trained by Defendants on how to properly insert the micro-inserts using the disposable delivery system and were given hysteroscopic equipment by Defendants.

109. In order to capture the market, Defendants independently undertook a duty of training physicians outside of FDA guidelines, including the implanting physicians, on how to properly use its own mechanism of delivery and the specialized hysteroscopic equipment manufactured by a third party.

110. Defendants' Senior Director of Global Professional Education stated, "training is the key factor when clinicians choose a new procedure" and, "For the Essure procedure, the patient is not under anesthesia, therefore a skilled approach is crucial."

111. In fact, because gynecologists and Plaintiffs' implanting physicians were unfamiliar with the device and how to deliver it, Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses where Defendants observed physicians until Defendants believed they were competent; (4) created Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiffs that "Physicians must be signed-off to perform Essure procedures."

112. Defendants provided no training to the implanting physicians on how to remove Essure should it fail.

113. Defendants also kept training records on all physicians "signed-off to perform Essure procedures".

114. In order to sell its product and because the implanting physicians did not have access to the expensive hysteroscopic equipment, Defendants provided the implanting physicians with hysteroscopic equipment which, although is not a part of Essure, is needed to implant Essure. The entrustment of this equipment is not part of any CPMA.

115. In fact, Defendants entered into agreements with Johnson & Johnson Co., Olympus America, Inc., Richard Wolf Medical Instruments Corp., and Karl Storz Endoscopy,

America, Inc. to obtain specialized hysteroscopic equipment to then give to physicians and to increase its sales force to promote Essure.

116. According to Defendants, these agreements allowed Defendants to "gain market presence…and expand … market opportunity by driving adoption among a group of physicians".

117. In regard to the entrustment of such specialized equipment, Defendants admitted: "We cannot be certain how successful these programs will be, if at all."

118. Defendants "handed out" this hysteroscopic equipment to unqualified physicians, including Plaintiffs' implanting physicians, in an effort to sell its product.

119. Defendants knew or failed to recognize that the implanting physicians were not qualified to use such specialized equipment yet provided the equipment to the unqualified implanting physicians in order to capture the market.

120. In return for providing the expensive hysteroscopic equipment, Defendants required that the implanting physicians purchase two Essure "kits" per month. This was part of Defendants' unreasonably dangerous and negligent distribution plan aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiffs.

121. The physicians had to purchase the kits regardless of whether they used them or not. This distribution plan created an environment which induced the implanting physicians to "push" Essure and implant the same into Plaintiffs.

122. Defendants used the expensive hysteroscopic equipment to induce the implanting physicians into an agreement as bait. Once the implanting physicians "took the bait", they were required to purchase two (2) Essure "kits" per month, regardless of whether they sold any Essure "kits".

123. Defendants' distribution plan also included (1) negligently distributing Essure in

violation of FDA orders and federal regulations; (2) marketing and selling an "adulterated" and "misbranded" product; (3) promoting Essure through representatives of the hysteroscopic equipment manufacturers who were not adequately trained, nor had sufficient knowledge regarding Essure; (4) failing to report and actively concealing adverse events which occurred as a result of Essure; (5) erroneously using non-conforming material and failing to keep track of the same in the manufacturing of Essure; (6) failing to use pre-sterile and post-sterile cages; (7) manufacturing Essure at an unlicensed facility; and (8) manufacturing Essure for three years without a license to do so.

124. In short, Defendants (1) failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians; (2) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use it; and (3) created an unreasonably dangerous distribution and reporting plan aimed at capitalizing and monopolizing the birth control market.

125. All of this was done in violation of federal law and its CPMA. Unfortunately, this was done at the expense of Plaintiffs' safety.

X

PLAINTIFFS' HISTORIES

126. As discussed in depth below, each of the Plaintiffs in this case has sustained serious physical injuries as a result of being implanted with the permanent birth control device, Essure®. As a result of (1) Defendants' negligence described *infra*; and (2) Plaintiffs' reliance on defendants' warranties, Defendants' Essure® devices have caused Plaintiffs serious personal injuries. As such, Plaintiffs have suffered a range of injuries such as ectopic pregnancy, actual pregnancy, abdominal pain, depression, fatigue, heavy bleeding, pain during intercourse, weight

fluctuations, severe back pain, and migraines. Additionally, some Plaintiffs' Essure® devices have migrated, perforated, and even become embedded in areas outside of the fallopian tubes. Moreover, some Plaintiffs have been forced to undergo hysterectomies in an effort to have their Essure® devices removed.

A. CALIFORNIA

1. Pam Wistrom

127. Plaintiff Pam Wistrom is a resident of Burbank, California.

128. On or about July of 2010, Pam Wistrom was implanted with an Essure device.

129. Sometime after implant of the Essure® device, Pam Wistrom began to experience one or more of the following symptoms including, but not limited to: severe abnormal menstrual pain, abnormal menstrual cycle, excessive bleeding, severe pelvic pain, migraines, abdominal pain, and dizziness. She reported to her healthcare provider that she was experiencing severe menstrual pain and bleeding.

130. As a result of Plaintiff's severe pain, cramping, and heavy bleeding, Plaintiff sought to have her Essure® removed.

131. Pam Wistrom had no choice but to undergo a hysterectomy which was to have the Essure device removed.

132. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as

to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

B. OHIO

1. <u>Bridget Chenault</u>

133. Plaintiff Bridget Chenault is a resident of Hillard, Ohio.

134. On or about July 12, 2008, Bridget was implanted with Essure® by Dr. Carol J. Greco at Matern Ohio Clinical Associates.

135. Sometime after implant of the Essure® device, Bridget Chenault began to experience one or more of the following symptoms including, but not limited to: severe abnormal menstrual pain, abnormal menstrual cycle, excessive bleeding, severe pelvic pain, migraines, abdominal pain, and dizziness. She reported to her healthcare provider that she was experiencing severe menstrual pain and bleeding.

136. As a result of Plaintiff's severe pain, cramping and heavy bleeding, Plaintiff sought to have her Essure® removed.

137. On or about July 12, 2012, Bridget Chenault underwent a hysterectomy which was performed by Dr. Carol J. Greco at Riverside Methodist Hospital in Columbus, Ohio.

138. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

2. Sherrilynn Andamasaris

139. Sherrilynn Andamasaris is a citizen of Girard, Ohio.

140. On or around April 18, 2012, Plaintiff Sherrilynn Andamasaris was implanted with Essure® by Dr. Antoine T. El-Hayek at Northside Medical Center in Youngstown, Ohio.

141. Sometime after implant of the Essure® device, Sherrilynn Andamasaris began to experience one or more of the following symptoms including, but not limited to: severe abnormal menstrual pain, abnormal menstrual cycle, excessive bleeding, severe pelvic pain, migraines, abdominal pain, and dizziness. She reported to her healthcare provider that she was experiencing severe menstrual pain and bleeding.

142. As a result of Plaintiff's severe pain, cramping and heavy bleeding, Plaintiff sought to have her Essure® removed.

143. Sherrilynn Andamasarias had no choice to undergo a hysterectomy to have the Essure device removed.

144. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

3. William Andamasaris

145. Plaintiff William Andamasaris is a resident of Girard, Ohio.

146. Plaintiff William Andamasaris is married to Plaintiff Sherrilynn Andamasaris and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

147. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

148. Plaintiff's wife experienced constant pain after being implanted with the Essure device to the extent that on some days he could not take care of the couple's children. As a result, Plaintiff would leave work and come home early to take care of the couple's children.

149. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores.

150. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure device as she suffered from pain during intercourse.

151. Plaintiff took his wife to and from doctor's appointments on several occasions, and tended to her physical well-being as she recovered from a hysterectomy.

152. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

4. <u>Rachel Kirby</u>

153. Plaintiff Rachel Kirby is a resident of North Ridgeville, Ohio.

154. In or around August of 2011, Plaintiff Rachel Kirby underwent the Essure® procedure in Parma, Ohio.

155. Immediately after implant of the Essure® device, Rachel Kirby began to

experience one or more of the following symptoms including, but not limited to: severe abnormal menstrual pain, abnormal menstrual cycle, and excessive bleeding.

156. As a result of Plaintiff's severe pain, cramping and heavy bleeding, Plaintiff sought to have her Essure® removed.

157. In or around May of 2015, Rachel Kirby underwent a hysterectomy to have the Essure device removed.

158. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®

5. Eugene Kirby

159. Plaintiff Eugene Kirby is a resident of North Ridgeville, Ohio.

160. Plaintiff Eugene Kirby is married to Plaintiff Rachel Kirby and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

161. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

162. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores.

163. Plaintiff took time off work to tend to his wife's physical well-being as she recovered from a hysterectomy.

164. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure device as she suffered from pain during intercourse.

165. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

6. Erin Kemp

166. Plaintiff Erin Kemp is a resident of Cincinnati, Ohio.

167. In or around 2013, Plaintiff Erin Kemp underwent the Essure® procedure at Bethesda North Hospital in Cincinnati, Ohio.

168. Plaintiff underwent an HSG, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

169. Sometime after implant of the Essure® device, Erin Kemp began to experience one or more of the following symptoms including, but not limited to: severe abnormal menstrual pain, abnormal menstrual cycle, excessive bleeding, severe pelvic pain, cramping, and bleeding.

170. As a result of Plaintiff's severe pain, cramping and heavy bleeding, Plaintiff sought to have her Essure® removed.

171. In or around 2014, Erin Kemp underwent a hysterectomy which was performed by Dr. Russell, at Christ Hospital in Cincinnati, Ohio.

172. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and,

based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®

7. Roy Kemp

173. Plaintiff Roy Kemp is a resident of Cincinnati, Ohio

174. Plaintiff Roy Kemp is married to Plaintiff Erin Kemp and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

175. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

176. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores.

177. Plaintiff took time off work to tend to his wife's physical well-being as she recovered from a hysterectomy.

178. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure device as she suffered from pain during intercourse.

179. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

C. NEW JERSEY

1. April Amission

180. Plaintiff April Amission is a resident of Forked River, New Jersey.

181. On or about November 3, 2009, Plaintiff underwent the Essure® procedure which was performed by Dr. Paul Vetter at Brick Women's Physicians, 87 Union Ave, Manasquan New Jersey.

182. On March 17, 2010, a Hysterosalpingogram confirmed complete occlusion of the fallopian tubes.

183. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual, abdominal, and back pain as well as heavy bleeding. In fact, Plaintiff's abdominal pain had at times been so severe that it has sent her to the emergency room.

184. On or about July 21, 2015, Plaintiff underwent Hysteroscopy, D&C, NuvaSure, endometrial ablation and laparoscopic left salpingo oophorectomy for abnormal bleeding and a left ovarian mass.

185. Plaintiff has a documented nickel allergy and has had systemic effects following Essure implant including but not limited to: Fatigue, weight gain, vision changes, dental problems, earaches, ringing in ears, sinus problems, mouth sores, hearing problems, chest pain, irregular heart beats, shortness of breath, frequent diarrhea, urgency to urinate, frequent urination, rashes, skin dryness, sores, numbness or tingling, memory difficulties, frequent headaches, joint pain, muscle pain, muscular weakness, loss of hair, cold intolerance, heat intolerance, easy bleeding, easy bruising, and frequent illness.

186. Additionally, Plaintiff may have to undergo a hysterectomy to remove the Essure device.

187. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and,

based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

2. Joe Amission

188. Plaintiff Joe Amission is a resident of Forked River, New Jersey.

189. Plaintiff Joe Amission is married to Plaintiff April Amission and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

190. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

191. Plaintiff's wife experienced constant pain after the Essure device was implanted to the extent that Plaintiff took several days off work to tend to his wife as she recovered from the procedure.

192. Additionally, since Plaintiff's wife was implanted with Essure®, he has been primarily responsible for tending to all household chores.

193. Further, the couple's level of sexual intimacy sharply declined as Plaintiff's wife suffers pain during intercourse.

194. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages

D. IOWA

1. Nicole McElroy

195. Plaintiff Nicole McElroy is a resident of Fairfield, Iowa.

196. Plaintiff underwent the Essure® procedure at University of Iowa Hospital and Clinic in Iowa City, Iowa, performed by D. Craig Syrup.

197. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe abdominal and back pain.

198. Additionally, after being implanted with Essure® Plaintiff began suffering from symptoms of depression and fatigue.

199. Plaintiff also began suffering weight fluctuations and pain during intercourse after undergoing the implantation of Essure®.

200. Since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

201. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have no choice but to undergo a hysterectomy to have her Essure® removed. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

2. <u>Tonya Palmer</u>

202. Tonya Palmer is a resident of Clinton, Iowa.

203. In or around 2005, Plaintiff Tonya Palmer underwent the Essure procedure.

204. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual, abdominal and back pain, fatigue, irregular and prolonged menstruation, and heavy bleeding.

205. In or about April of 2014, Tonya Palmer underwent an endometrial cryoablation to treat the excessive bleeding. Despite undergoing this procedure, she continued to experience heavy bleeding, and was subsequently prescribed Depo Provera to further control the bleeding.

206. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have no choice but to undergo a hysterectomy to have her Essure® removed. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®

E. TEXAS

1. <u>Christina Baker</u>

207. Plaintiff Christina Baker is a resident of Keller, Texas.

208. On or around May 26, 2016, Plaintiff Christina Baker underwent the Essure® procedure by Edward D. Clark MD at 1526 Windsor Forest, North Lake, Texas.

209. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual and abdominal pain as well as heavy bleeding.

210. Additionally, after being implanted with Essure® Plaintiff began suffering from symptoms of fatigue.

211. Plaintiff also experienced weight fluctuations and pain during intercourse after being implanted with Essure®.

212. After undergoing the Essure® procedure Plaintiff suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

213. Plaintiff's Essure®-related pain became so bad that she was eventually prescribed Norco as treatment.

214. On or around August 6, 2015, Plaintiff underwent the laparoscopic removal of her fallopian tubes and Essure® due to perforation and migration of one of her Essure® coils.

215. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. As a result, Plaintiff suffered from severe menstrual and abdominal pain, as well as fatigue, heavy bleeding, weight fluctuations and migraines. Additionally, Plaintiff had no choice but to undergo a hysterectomy in order to have her Essure® coils removed. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentation as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning the safety and effectiveness of Essure® and suffered severe and

F. ARKANSAS

1. Linda Helloms

216. Plaintiff Linda Helloms is a resident of White Hall, Arkansas.

217. In or around June of 2007, Plaintiff Linda Helloms underwent the Essure® procedure performed by Dr. Christy Walker at Walker Healthcare for Women located in Pine Bluff, Arkansas.

218. Approximately one (1) year after undergoing the Essure® procedure, Plaintiff began to suffer frequent menstrual cycles, heavy bleeding, severe menstruation pain, painful intercourse, cramping, bloating, hormonal changes, abdominal pain, and migraines.

219. Additionally, Plaintiff also suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

220. Plaintiff's Essure®-related pain became so severe that she underwent a partial hysterectomy on March 6, 2017, to have Essure® removed. The hysterectomy was performed by Dr. Clint Hutchinson at Baptist Hospital in Little Rock, Arkansas.

221. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

2. <u>Charles Helloms</u>

222. Plaintiff Charles Helloms is a resident of White Hall, Arkansas.

223. Plaintiff Charles Helloms is married to Plaintiff Linda Helloms and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

224. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

225. Plaintiff's wife experienced constant pain after being implanted with the Essure device to the extent that she could not take care of the couple's children. As a result, Plaintiff was primarily responsible for child care.

226. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores.

227. Plaintiff also exhausted all of his vacation and sick time leave from work to tend to Plaintiff's wife's physical well-being as she recovered from a hysterectomy.

228. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure device as she suffered from pain during intercourse.

229. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

G. MISSISSIPPI

1. Shaqueena Loper

230. Plaintiff Shaqueena Loper is a resident of Forest, Mississippi.

231. In or around August of 2013, Plaintiff Shaqueena Loper underwent the Essure® procedure performed by Dr. Missy McMinn at Surgicare of Jackson in Jackson, Mississippi.

232. Approximately one (1) year after undergoing the Essure® procedure, Plaintiff began to suffer irregular and prolonged menstruation, heavy bleeding, painful intercourse, severe abdominal pain, cramping, and bloating.

233. Plaintiff has also suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

234. Additionally, after being implanted with Essure® Plaintiff was made aware by her physician that she had developed cysts and fibroids on her ovaries, and that Essure® had migrated and imbedded itself on the left-hand side of the Plaintiff's uterus.

235. Plaintiff's Essure®-related pain became so severe that she underwent a partial hysterectomy on May 18, 2017, to have Essure® removed. The hysterectomy was performed by Dr. Leigh Edwards at Merit Health River Oaks in Flowood, Mississippi.

236. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

2. <u>Clarence Loper</u>

237. Plaintiff Clarence Loper is a resident of Forest, Mississippi.

238. Plaintiff Clarence Loper is married to Plaintiff Shaqueena Loper and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

239. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

240. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores.

241. Plaintiff took his wife to and from doctor's appointments on several occasions, and tended to her physical well-being as she recovered from a hysterectomy.

242. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure device as she suffered from pain during intercourse.

243. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

H. GEORGIA

1. DARLISSHA SADLER

244. Plaintiff Darlissha Sadler is a resident of Conyers, Georgia.

245. On or around October 2010, Plaintiff underwent the Essure® procedure performed at DNC Outpatient Physician Clinic in Southville, Michigan.

246. Plaintiff underwent an HSG, during which it was confirmed that her fallopian tubes were occluded.

247. Immediately after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain and bleeding, painful intercourse, severe abdominal pain, cramping, and bloating.

248. Additionally, Plaintiff also suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

249. Additionally, Plaintiff had no choice but to undergo a partial hysterectomy wherein she had her fallopian tubes excised to have the Essure device removed.

250. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

I. VIRGINIA

1. Saudia Jones

251. Plaintiff Saudia Jones is a resident of Newport News, Virginia.

252. In or around October of 2014, Plaintiff Saudia Jones underwent the Essure® procedure at Peninsula Women's Care in Newport News, Virginia.

253. Plaintiff underwent an HSG, during which it was confirmed that her fallopian tubes were occluded.

254. Immediately after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual, abdominal, and back pain, as well as heavy bleeding.

255. Currently, Plaintiff is seriously considering having her Essure® removed.

256. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have no choice but to undergo a hysterectomy to have her Essure® removed. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants'

misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

J. TENNESSEE

1. **Tiffany Dowdy**

257. Plaintiff Tiffany Dowdy is a resident of Clarksville, Tennessee.

258. In or around March of 2012, Plaintiff Tiffany Dowdy underwent the Essure® procedure at the Vanderbilt University Hospital in Nashville, Tennessee.

259. Plaintiff underwent an HSG, during which it was confirmed that her fallopian tubes were occluded.

260. Immediately after undergoing the Essure® procedure, Plaintiff began to suffer irregular and prolonged menstruation, severe menstrual, abdominal and back pain, pain during intercourse, cramping and bloating, as well as heavy bleeding. Plaintiff continues to experience these symptoms on a daily basis.

261. Plaintiff's severe abdominal pain and heavy bleeding caused her to go to the emergency room on three (3) separate occasions beginning June of 2012. Doctors ran an HSG test on the Plaintiff during all three (3) emergency room visits and determined her HSG levels were above 500.

262. Since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

263. In or around 2013, Plaintiff was informed by her primary physician, Dr. David Boles, that he symptoms were likely being caused by the Essure device.

264. Currently, Plaintiff is seriously considering having her Essure® removed. Her

physician has recommended a hysterectomy.

265. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have no choice but to undergo a hysterectomy, a life changing procedure, to have her Essure® removed. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

2. <u>Ericka Snoddy</u>

266. Plaintiff Ericka Snoddy is a resident of Knoxville, Tennessee.

267. In or around June of 2009, Plaintiff Erika Snoddy underwent the Essure® procedure performed by Dr. Curtis Elam at Fort Sanders Regional Hospital in Knoxville, Tennessee.

268. Plaintiff underwent an HSG, during which it was confirmed that her fallopian tubes were occluded.

269. Approximately two (2) years after undergoing the Essure® procedure, Plaintiff began to suffer irregular and prolonged menstruation, severe menstrual, abdominal and back pain, painful intercourse, cramping and bloating, as well as heavy bleeding.

270. Since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

271. In September of 2016, Plaintiff had no choice but to undergo a hysterectomy in order to have her Essure® device removed. The hysterectomy was performed by Plaintiff's Gynecologist, Dr. Cece at the Parkwest Medical Center in Knoxville Tennessee.

272. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

K. MICHIGAN

1. Terry Page

273. Plaintiff Terry Page is a resident of Detroit, Michigan.

274. On or around 2003, Plaintiff Terry Page underwent the Essure® procedure performed by Dr. Leon Hochman at Southfield Obstetrics & Gynecology in Southfield.

275. Plaintiff underwent an HSG, during which it was confirmed that her fallopian tubes were occluded.

276. Approximately two (2) years after undergoing the Essure® procedure, Plaintiff began to suffer severe menstruation pain, heavy bleeding, painful intercourse, severe abdominal pain, cramping and bleeding.

277. On or around 2012, Plaintiff had no choice but to undergo a partial a hysterectomy to remove Essure®.

278. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a

safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

2. Anthony Page

279. Plaintiff Anthony Page is a resident of Detroit, Michigan.

280. Plaintiff Anthony Page is married to Plaintiff Terry Page and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

281. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

282. Plaintiff's took approximately one week off work to care for his wife's physical well-being as she recovered from a hysterectomy.

283. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores.

284. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure device as she suffered from pain during intercourse.

285. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. Julie Pung

286. Plaintiff Julie Pung is a resident of Lansing, Michigan.

287. In or around 2009, Plaintiff Julie Pung underwent the Essure® procedure which was performed by Dr. Andrew Zink at Ingham Regional Medical Hospital in Lansing, Michigan.

288. Plaintiff underwent an HSG, during which it was confirmed that only her right fallopian tube was occluded.

289. Approximately one (1) year after undergoing the Essure® procedure, Julie Pung began to experience one or more of the following symptoms, including, but not limited to: severe abnormal menstrual pain, abnormal menstrual cycle, excessive bleeding, severe pelvic pain, migraines, abdominal pain, and dizziness.

290. Since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

291. Plaintiff's Essure®-related pain became so severe that she underwent a hysterectomy in or around August of 2013, to have Essure® removed which was performed by Dr. Kelley at Sparrow Hospital in Lansing, Michigan.

292. It was determined that the Essure device did not perform as warranted and instead had fractured and migrated causing injuries as noted above.

293. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to

her detriment on Defendants' misrepresentations concerning Essure®.

L. NORTH CAROLINA

1. Jennifer DeAlmeida

294. Plaintiff Jennifer DeAlmeida is a resident of Wilmington, North Carolina.

295. On or about 2007, Plaintiff Jennifer DeAlmeida underwent the Essure® procedure performed by Dr. Al Hussein at Lake Norman in Mooresville, North Carolina.

296. Plaintiff underwent an HSG, during which it was confirmed that her fallopian tubes were occluded.

297. Immediately after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual, abdominal and back pain, heavy bleeding, cramping and bloating, painful intercourse, and irregular and prolonged menstruation.

298. Additionally, sometime after the Essure procedure Plaintiff developed a serious infection resulting in prolonged hospitalization.

299. Plaintiff also developed cysts in her gall bladder. Plaintiff's gall bladder was ultimately removed.

300. Since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

301. As a result of Plaintiff's severe pain, cramping and heavy bleeding, Plaintiff sought to have her Essure® removed.

302. In or around 2009, Plaintiff underwent a hysterectomy to remove the Essure device which was performed by Dr. Al Hussein at Lake Norman in Mooresville, North Carolina.

303. During the hysterectomy, Dr. Al Hussein determined that Plaintiff was suffering

from severe endometriosis. A biopsy was performed, and Jennifer DeAlmeida was subsequently diagnosed with uterine cancer.

304. In or around 2016, Jennifer DeAlmeida began to experience back pain. She sought treatment from orthopedic specialist, Dr. Robert Rodger in Wilmington, North Carolina. An MRI scan revealed that a foreign object is lodged in Plaintiff's spine.

305. Plaintiff's medical providers have informed her that they believe the foreign object to be part of the Essure device which may have fractured and migrated to her spine.

306. Plaintiff will another MRI this year, 2017, and proceed with further treatment to remove the foreign object.

307. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning Essure®.

2. <u>Jarbas DeAlmeida</u>

308. Plaintiff Jarbas DeAlmeida is a resident of Wilmington, North Carolina.

309. Plaintiff Jarbas DeAlmeida is married to Plaintiff Jennifer DeAlmeida and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

310. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

311. Plaintiff and his wife owned two restaurants. As a result of the constant pain that Plaintiff's wife experienced after the Essure device was implanted, Plaintiff became primarily responsible for running the family businesses.

312. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores and child care.

311. Plaintiff took his wife to and from doctor's appointments on a recurrent basis for approximately three (3) years, and tended to her physical well-being as she recovered from infections, a hysterectomy, and uterine cancer after the Essure implant.

312. Plaintiff and his wife were forced to close the family business which caused Plaintiff and his wife financial stress, mental, and emotional anguish.

313. Plaintiff 's own health diminished thereafter to the extent that he experienced a heart attack.

314. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure device as she suffered from pain during intercourse.

315. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

M. OKLAHOMA

1. Megan Berryhill

316. Plaintiff Megan Berryhill is a resident of Ardmore, Oklahoma.

317. In or around August of 2010, Plaintiff Megan Berryhill underwent the Essure® procedure performed at Southern Oklahoma Women's Center in Admore, Oklahoma.

318. Plaintiff underwent an HSG, during which it was confirmed that her fallopian

tubes were occluded.

319. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual, abdominal and back pain as well as heavy bleeding.

320. Plaintiff underwent an endometrial ablation to treat her abnormal uterine bleeding.

321. Since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

322. As a result of Plaintiff's severe pain, cramping and heavy bleeding, Plaintiff sought to have her Essure® removed.

323. Additionally, Plaintiff had no choice but to undergo a hysterectomy to remove Essure®.

324. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentation as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning the safety and effectiveness of Essure® and suffered severe and continuing injuries as a result.

2. <u>Shyra Isham</u>

325. Plaintiff Shyra Isham is a resident of Oklahoma City, Oklahoma

326. In or around August of 2002, Plaintiff Shyra Isham underwent the Essure®

procedure at Southcrest Medical Center in Tulsa, Oklahoma.

327. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual, abdominal and back pain, cramping and bloating, irregular and prolonged menstruation, as well as heavy bleeding.

328. Since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

329. Plaintiff has a documented nickel allergy and has had systemic effects following Essure implant including but not limited to: Fatigue, weight gain, vision changes, dental problems, earaches, ringing in ears, sinus problems, mouth sores, hearing problems, chest pain, irregular heart beats, shortness of breath, frequent diarrhea, urgency to urinate, frequent urination, rashes, skin dryness, sores, numbness or tingling, memory difficulties, frequent headaches, joint pain, muscle pain, muscular weakness, loss of hair, cold intolerance, heat intolerance, easy bleeding, easy bruising, and frequent illness.

330. Additionally, Plaintiff had no choice but to undergo a hysterectomy to have her Essure® removed.

331. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentation as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning the safety and effectiveness of

Essure® and suffered severe and continuing injuries as a result.

N. MICHIGAN

1. Nadine Meal

332. Plaintiff Nadine Meal is a resident of Roseville, Michigan.

333. In or around August of 2008, Plaintiff Nadine Meal underwent the Essure® procedure at Beaumont Hospital in Sterling Heights, Michigan.

334. Plaintiff underwent an HSG, during which it was confirmed that her fallopian tubes were occluded.

335. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual, abdominal and back pain, cramping and bloating, irregular and prolonged menstruation, as well as heavy bleeding.

336. Additionally, Plaintiff may have no choice but to undergo a hysterectomy to have her Essure® removed.

337. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentation as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning the safety and effectiveness of Essure® and suffered severe and continuing injuries as a result.

N. KANSAS

1. Joyce Snotgrass

338. Plaintiff Joyce Snotgrass is a resident of Eudora, Kansas.

339. In or around May of 2012, Plaintiff Joyce Snotgrass underwent the Essure® procedure at Lawrence Memorial Hospital in Lawrence, Kansas.

340. Approximately one (1) year after undergoing the Essure® procedure, Plaintiff began to suffer severe abdominal pain on a daily basis.

341. Additionally, Plaintiff stopped menstruating.

342. Plaintiff's abdominal pain grew so severe that she underwent exploratory surgery at Lawrence Memorial Hospital in Lawrence, Kansas, which was performed by Dr. Tiffanie Mercardo.

343. It was determined during the exploratory surgery that the Essure device had migrated, perforated, and became embedded in areas outside of Plaintiff's fallopian tubes.

344. Plaintiff's Essure®-related pain became so severe that she underwent a hysterectomy on March 23, 2017, to remove the device. The procedure was performed by Dr. Tiffinie Mercado at the Lawrence Memorial Hospital in Kansas.

345. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentation as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendants' misrepresentations concerning the safety and effectiveness of Essure® and suffered severe and continuing injuries as a result.

XI

FRAUDULENT CONCEALMENT/DISCOVERY RULE/EQUITABLE TOLLING/EQUITABLE ESTOPPEL

A. Summary of Active Concealment

346. Defendants' fraudulent acts and/or omissions prevented Plaintiffs and/or Plaintiffs' physicians from discovering the injuries or causes thereof as alleged in this amended complaint until February 29, 2016.

347. Defendants' failure to report, document, or follow up on the known adverse event complaints, and concealment and altering of adverse events, serious increased risks, dangers, and complications, constitutes fraudulent concealment that tolls Plaintiffs' statutes of limitations.

348. Defendants are also estopped from relying on any statute of limitations defense because they continued to refute and deny reports and studies questioning the safety of Essure, actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure, and failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and Plaintiffs. As a result of Defendants' concealment of the true character, quality, history, and nature of their product, they are estopped from relying on any statute of limitations defense.

349. Defendants furthered their fraudulent concealment through acts and omissions, including misrepresenting known dangers and/or defects in Essure and/or arising out of the use of Essure and a continued and intentional, systematic failure to disclose and/or conceal such information from/to Plaintiffs, Plaintiffs' physicians, and the FDA.

350. In short, Defendants:

a. Actively and intentionally concealed from Plaintiffs that their physicians were not trained pursuant to FDA-approved training.

b. Actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure, and failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and Plaintiffs.

c. Actively and intentionally concealed from Plaintiffs and Plaintiffs' physicians risks by making the misrepresentations/warranties discussed herein knowing they were false. In short, Defendants knew the misrepresentations were false because they had studies and reports which showed the opposite, yet altered and concealed the same from Plaintiffs, the FDA and Plaintiffs' physicians. Defendants made the misrepresentations with the intent of misleading Plaintiffs into relying on them because they had studies and reports which showed the opposite, yet decided to conceal the same (collectively "the acts and omissions").

351. If Defendants had met their duties under the applicable federal and parallel state laws, the FDA would have had the information necessary to warn the public, including Plaintiffs and Plaintiffs' physicians, of the increased risks and serious dangers associated with Essure in time to have lessened or prevented Plaintiffs' injuries, which is evidenced by the fact that the FDA is now mandating a new clinical trial, a "black box" warning, and a "patient decision checklist" which discusses and warns in detail about the risks of the very same injuries Plaintiffs suffered. Had Defendants satisfied their obligations, these FDA mandates would have been implemented prior to Plaintiffs' implantations. However, Defendants continued to misrepresent the safety and efficacy of Essure at the FDA Hearings.

352. In short, Defendants manipulated their reports to the FDA and presented false and misleading information, which, in turn, resulted in Plaintiffs' consent to implant not being informed because critical facts regarding the nature and quality of side effects from Essure were

concealed from Plaintiffs and their physicians.

353. Defendants did this in an effort to maintain the impression that Essure had a positive risk/benefit profile, to guard sales, and to ensure that Plaintiffs and their physicians did not have the salient facts in order to bring the claims alleged in this amended complaint.

354. Defendants' conduct was malicious, intentional, and outrageous, and constitutes a willful and wanton disregard for the rights and safety of Plaintiffs and others.

B. FDA Calls Essure Meeting

355. The FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to hear concerns from experts and plan recommendations for Essure.

356. On February 29, 2016, the FDA first announced that it will force a major change to the Essure warning label and also require all women considering receiving Essure, to fill out a "Patient Decision Checklist" to ensure that they are fully informed of the true risks.[3]

357. The FDA stated that such warnings are needed for a woman to understand the risks as compared to alternative options and then decide whether the product is right for her.[4]

358. The new warning and checklist changed the risk/benefit profile of Essure for Plaintiffs and gave rise to new salient facts which Plaintiffs and their physicians did not and could not have had prior to February 29, 2016.

359. In its current form, this patient decision checklist requires a patient's initials and signature fifteen separate times, recognizing new risks previously not disclosed.

360. Finally, women considering Essure will have the chance to be fully informed of

[3] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm.

[4] *Id.*

its true risks.

361. This result is why Defendants withheld and actively concealed safety information from the FDA and the public for years.

362. Upon information and belief, Defendants knew that if the true risks of Essure were known to the FDA, they should or would inevitably be communicated to physicians and Plaintiffs.

363. The checklist specifically warns of device migration, perforation of organs, and new side effects that Defendants had been cited for hiding from the FDA, Plaintiffs, and Plaintiffs' physicians and/or enhances prior inadequate warnings.

364. The checklist enhances the sufficiency of the warnings given to potential Essure patients and completely alters the process of undergoing the procedure.

365. The checklist has a major impact on the risk/benefit profile of the device, and Plaintiffs would not have had the device implanted if they were aware of the true risks of Essure.

366. On February 29, 2016, the FDA also announced that it would require a detailed boxed warning for the Essure device. The FDA reserves boxed warnings, commonly referred to as "black box warnings," for only the most serious adverse events. Boxed warnings indicate the highest level of risk.

367. The FDA suggested the following warning:

> **WARNING: Some patients implanted with the Essure System for Permanent Birth Control have reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions. Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure device during discussion of the benefits and risks of the device.[5]**

[5] *FDA Draft Guidance on Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, issued March 4, 2016.*

368. This boxed warning directly addresses side effects that Defendants had been cited for hiding from the FDA and the public for years.

C. Discovery Rule – Tolling

369. Plaintiffs did not know of the claims and their underlying facts asserted in this amended complaint, nor could any reasonable prudent person know of such claims until February 29, 2016.

370. Plaintiffs did not possess the sufficient critical facts to put them on notice that the wrongs and the acts and omissions discussed herein had been committed until such date. This is because it was not until the FDA hearing that Essure's safety and Defendants' acts and omissions were publicly called into question by the FDA and the medical community and the FDA required the "black box warning," "patient decision checklist," and "new clinical trials."

371. In fact, no reasonable person in Plaintiffs' position would have been aware of the salient facts set out in this amended complaint until after February 29, 2016.

372. Plaintiffs did not have the opportunity to discover the harm inflicted because Defendants were and are continuing to conceal the acts and omissions noted above.

373. At all times material hereto, Plaintiffs exercised reasonable diligence in investigating potential causes of their injuries by discussing their injuries with healthcare providers. None of the conversations gave Plaintiffs a reason to suspect, or reasonably should have given Plaintiffs a reason to suspect, that Essure or Defendants' tortious conduct was the cause of such injuries until February 29, 2016.

374. Regardless of the exercise of reasonable diligence, Plaintiffs did not know, or reasonably should not have known, that they suffered injuries and that their injuries were caused by Defendants' conduct until February 29, 2016.

375. Plaintiffs neither suspected nor knew of Defendants' wrongdoings as alleged herein until February 29, 2016.

376. In sum, Plaintiffs were reasonably unaware, and had no reasonable way of knowing, that their injuries described above were caused by Defendants' conduct until February 29, 2016.

377. As such, Plaintiffs' statute of limitations did not begin to run until February 29, 2016.

D. Fraudulent Concealment – Equitable Tolling

378. Defendants committed affirmative independent acts of concealment (including the acts and omissions) and intentionally mislead Plaintiffs as noted above upon which Plaintiffs and Plaintiffs' physicians relied on.

379. These acts and omissions misled Plaintiffs in regard to their causes of action and prevented them from asserting such rights because the facts which would support their causes of action as alleged in this amended complaint were not apparent to a reasonably prudent person until February 29, 2016.

380. Defendants also prevented Plaintiffs from asserting their rights by committing affirmative independent acts of concealment as noted above upon which Plaintiffs relied.

381. Due to the acts and omissions of concealment, Plaintiffs were not cognizant of the facts supporting their causes of action until February 29, 2016.

382. As such, Plaintiffs' statutes of limitations were tolled in light of Defendants' fraudulent concealment and their statutes began to run starting from the date that facts supporting their causes of action in this amended complaint became apparent, which was on or after February 29, 2016.

383. Defendants' misconduct and fraudulent concealment of the relevant facts deprived Plaintiffs and their physicians of vital information essential to the pursuit of the claims in this amended complaint, without any fault or lack of diligence on their part. Plaintiffs relied on Defendants' misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendants' tortious conduct.

E. Equitable Estoppel

384. In the alternative, Defendants are estopped and may not invoke the statute of limitations as a defense because, through the fraud or concealment noted above, specifically the acts and omissions, Defendants caused Plaintiffs to relax their vigilance and/or deviate from their right of inquiry into the facts as alleged in this amended complaint.

385. Defendants affirmatively induced Plaintiffs to delay bringing this amended complaint by the acts and omissions.

386. In addition to the acts and omissions noted above, Defendants consistently represented to Plaintiffs and/or Plaintiffs' physicians that Essure was not the cause of any of Plaintiffs' injuries to delay their bringing a claim against Defendants.

387. Defendants are and were under a continuing duty to monitor and disclose the true character, quality, and nature of Essure. Because of Defendants' misconduct and fraudulent concealment of the true character, quality, and nature of its device, Defendants are estopped from relying on any statute of limitations defense.

XII

FACTS AND WARRANTIES

388. Defendants failed to abide by FDA approved training guidelines when training

Plaintiffs' implanting physicians on how to use Essure and the necessary hysteroscopic equipment.

389. The skills needed to place the micro-inserts, as recognized by the FDA panel in the PMA process, "are way beyond the usual gynecologist".

390. Defendants went out and attempted to train the implanting physicians on how to use its device and the necessary hysteroscopic equipment. Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses where Defendants observed physicians until Defendants believed they were competent; (4) created Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiffs that "Physicians must be signed-off to perform Essure procedures". Defendants had no experience in training others in hysteroscopy.

391. Defendants failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians and provided hysteroscopic equipment to the implanting physicians who were not qualified to use such complicated equipment.

392. A key study found that a learning curve for this hysteroscopic procedure was seen for procedure time, but not for successful placement, pain, and complication rates, evidencing that Defendants' training methods were failing[6].

393. Defendants provided hysteroscopic equipment to the implanting physicians who were not competent to use such equipment. Defendants knew the implanting physicians were not competent to use such sophisticated equipment, yet provided the equipmentregardless in order to sell its product.

394. Defendants' distribution plan of requiring the implanting physicians to purchase

[6] *Learning curve of hysteroscopic placement of tubal sterilization micro inserts*, US National Library of Medicine, Janse, JA.

two (2) Essure kits a month was an unreasonably dangerous plan, as it compelled the implanting physicians to insist that Essure be used in Plaintiffs.

395. Defendants' distribution plan also included (1) negligently distributing an "adulterated" and "misbranded" device against its CPMA and federal law; (2) the promotion of Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (3) failing to report and actively concealing perforations which occurred as a result of Essure; (4) erroneously using non-conforming material in the manufacturing of Essure and failing to keep track of the non-conforming material; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure at an unlicensed facility and (7) manufacturing Essure for three years without a license to do so.

396. Lastly, Plaintiffs relied on several warranties which were given directly by Defendants to Plaintiffs, prior to implantation, on the internet and in the implanting physicians' offices, through Defendants' website and advertising, as outlined in detail *infra*.

XIII

COUNTS

A. NEGLIGENT TRAINING – COUNT I

397. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

398. First, Defendants undertook an independent duty to train physicians on how to properly use Essure and place the micro-inserts which failed to abide by FDA training guidelines.

399. In fact, Defendants (1) created an Essure Training Program; (2) created a simulator called EssureSim; (3) organized limited training courses where Defendants observed

physicians until Defendants believed they were competent; (4) created Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiffs that "Physicians must be signed-off to perform Essure procedures."

400. As part of Defendants' training, Defendants had a duty to abide by the FDA training guidelines for the implanting physicians on how to place Essure using its own delivery system, certify the implanting physicians, and oversee this particular procedure. Defendants also had a duty to disclose adverse events to the physicians so that they, in turn, could properly advise their patients of the actual risks.

401. Specifically, pursuant to the FDA approved training regulations and guidelines, Defendants had a duty to comply with the following federal requirements so that implanting physicians performed "competent procedures" and would be able to "manage possible technical issues":

(a) Ensure that the implanting physicians completed the required preceptoring (generally 5 cases) in Essure placement until competency;

(b) Ensure that the implanting physicians had read and understood the Physician Training Manual;

(c) Ensure that the implanting physicians had "successful completion of Essure Simulator Training";

402. As outlined in the Physicians Manual these requirements were necessary in order to:

(a) Ensure that the implanting physicians were selecting appropriate patients for Essure;

(b) Ensure that the implanting physicians were appropriately counseling Plaintiffs on the known risks; and

(c) Ensure the implanting physicians were qualified and competent to perform the Essure procedure to ensure proper placement to preclude migration, perforation and fracturing of coils.

403. Defendants breached this duty and parallel state laws, thereby departing from the FDA approved guidelines by:

(a) Not ensuring that the implanting physicians completed the required preceptoring in Essure placement until competency. The implanting physicians did not complete the required preceptoring until competency;

(b) Not ensuring that the implanting physicians had read and understood the Physician Training Manual. The Implanting Physicians did not understand the Physician Training Manual.

(c) Not ensuring that the implanting physicians had "successful completion of Essure Simulator Training". The implanting physicians did not successfully complete the Essure Simulator Training.

404. This departure from the training guidelines caused the Essure coils to migrate/fracture and/or perforate organs because:

(a) The Essure Training Program ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above;

(b) The required preceptoring ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above;

(c) The requirement to read and understand the Physician Training Manual ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above.

405. This breach caused Plaintiffs' damages as noted above.

406. As a result of Defendants' negligence individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

407. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

408. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

409. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies, along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

410. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

B. NEGLIGENCE – RISK MANAGEMENT – COUNT II

411. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

412. In short, Defendants had a duty, under both state and federal law, to have in place a reasonable risk management procedure to ensure that, *inter alia*, (1) adverse events were being reported to the FDA so that it could be relayed to the implanting physicians and/or Plaintiffs; (2) adverse reports were considered in its risk analysis and that the risk analysis was updated to reflect the same so that it could be relayed to the implanting physicians and/or Plaintiffs; (3) Defendants investigated information about the risks Essure posed so that it could be relayed to

the implanting physicians and/or Plaintiffs; (4) the continued sale of Essure was appropriate and reasonable despite information being withheld from the public by Defendants; (5) Defendants monitored the product after pre-market approval to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.; (6) Defendants had internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq., and §§ 820.20 et seq.; and (7) Defendants maintained the labeling of Essure by filing a "Special PMA Supplement – Changes Being Effected" ("CBE") which allowed Defendants to unilaterally update the labeling of Essure to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d).

413. Specifically, Defendants had a duty to comply with the following federal regulations, but breached these regulations by the subsequent violations noted directly below (which Defendants were cited for by the FDA):

(a) 21 C.F.R. 814.80 – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a condition of approval specified in the PMA approval order for the device.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians. This failure to disclose and include the information in their risk management analysis was a condition of approval in its CPMA.)

(b) 21 C.F.R. 803.1(a) – This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also

submit specified follow up information. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(c) 21 C.F.R. 803.10 – (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us. (2) Submit annual reports (described in 803.33) to us. (b) If you are an importer, you must submit reports (described in subpart D of this part), as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or (ii) Submit reports of device-related malfunctions to the manufacturer. (2) [Reserved]. (c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction. (2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of: (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or (ii) A reportable event for which we made a written request. (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(d) 21 C.F.R. 803.50(a) – (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a

death or serious injury, if the malfunction were to recur. (b) What information does FDA consider "reasonably known" to me? (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you: (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device. (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(e) 21 C.F.R. 803.53 – You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than 5 work days after the day that you become aware that: (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or (b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(f) 21 C.F.R. 806.10 – (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated

by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device; or (2) To remedy a violation of the act caused by the device, which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b). (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal. (c) The manufacturer or importer shall include the following information in the report: (1) The seven-digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven-digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven-digit registration number will be assigned a seven-digit central file number by the district office reviewing the reports. (2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal. (3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device. (4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA. (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number. (6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report. (7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken. (8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers. (9) The total number of devices manufactured or distributed subject to the correction or removal

and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal. (10) The date of manufacture or distribution and the device's expiration date or expected life. (11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee. (12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section. (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted. (d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available. (e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury. (f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter. [62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013].

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(g) 21 C.F.R. 814.84 – (a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device. (b) Unless FDA specifies otherwise, any periodic report shall: (1) Identify changes described in 814.39(a) and changes required to be

reported to FDA under 814.39(b). (2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA: (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant. (ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted. (3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter. (4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(h) 21 C.F.R. 820.65 – Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

(Defendants breached this federal standard by failing to establish and maintain procedures for identification of each Essure unit which in turn precluded proper corrective actions and led to the failure to disclose and include in their risk management analysis thousands of adverse events and complaints for migrations, perforations, pregnancies, and device failures and malfunctions, which in turn were never disclosed to Plaintiffs and Implanting Physicians. This failure to disclose and include in their risk management analysis was a condition of approval in its CPMA).

(i) 21 C.F.R. 822 – Post market surveillance. This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (FDCA) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria: (a) Failure of the device would be reasonably likely to have serious adverse health consequences; (b) The device is intended to be implanted in the human

body for more than one (1) year;… The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. This data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

(Defendants were cited for and breached this federal standard by failing to comply with postmarket surveillance plans. Specifically, by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians. Defendants further breached this federal standard by not withdrawing its product from the market.)

(j) 21 C.F.R. 820.180 – All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(k) 21 C.F.R. 820.198 – (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another

investigation is not necessary. (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include: (1) The name of the device; (2) The date the complaint was received; (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; (4) The name, address, and phone number of the complainant; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action taken; and (8) Any reply to the complainant. (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(l) FDA requirement in CPMA order – "Within 10 days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(m) FDA requirement in CPMA order – "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests

that the device may have caused or contributed to a serious injury."

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(n) Monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq..

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physician.)

(o) Establish internal procedures for reviewing complaints and event reports, 21 CFR §§820.198, §§ 820.100 et seq. and §§ 820.20 et seq.

(Defendants were cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

414. Due to these breaches, Defendants were cited by the FDA as Defendants "did not consider these complaints in their risk analysis" and "for their risk analysis of Essure being incomplete".

415. This was an unreasonably dangerous and negligent risk analysis plan which was required by federal law as it put Plaintiffs at unnecessary risk of injury due to Defendants' failure to report adverse reports to the FDA, to track non-conforming product, update its labeling of Essure, and to consider adverse reports in its risk analysis.

416. This breach caused Plaintiffs' damages because but for Defendants' failure to comply with federal law and disclose, consider, and include in their risk management plans and/or labeling the thousands of adverse events and complaints for migrations, perforations,

pregnancies, device failures and malfunctions, Plaintiffs would not have been implanted with Essure and therefore would also not have been injured by Essure. Instead, Defendants failed to have a complete Risk Management Plan in place, thereby precluding Plaintiffs and their implanting physicians from knowing of the thousands of migrations, perforations, pregnancies, device failures and malfunctions. This was actively concealed by Defendants.

417. This breach caused Plaintiffs' injuries and damages noted above.

418. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

419. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment, and rehabilitation into the indefinite future.

420. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

421. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies, along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

422. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and

suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

C. BREACH OF EXPRESS WARRANTY – COUNT III

423. Plaintiffs re-allege and re-incorporate the preceding paragraphs and plead in the alternative to Counts IV.

424. The FDA's CPMA order confirms that: the FDA "does not evaluate information related to contractual liability warranties, however, you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

425. This claim arises out of injuries caused by Defendants' express warranties to Plaintiffs which were specifically negotiated and expressly communicated to Plaintiffs by Defendants or its agents in such a manner that Plaintiffs understood and accepted them.

426. Defendant made, and Plaintiffs relied on, the following actual affirmations of fact or promises which formed the bases of the bargain between Plaintiffs and Defendants[7]:

a. "Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty which was located on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

b. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of

[7] The warranties and misrepresentations relating to pregnancy apply to only those plaintiffs that became pregnant.

commercial experience. Defendants concealed this information from Plaintiffs. "There were Zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiffs.

c. "Physicians must be signed-off to perform Essure procedures"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted reliable physicians who were approved to perform their surgery.

iii. However, this warranty was false as Defendants failed to abide by FDA guidelines when training the implanting physicians and "signed-off" on the implanting physicians who did not have the requisite training. Defendants concealed this information from Plaintiff.

iv. "Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy"

v. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

vi. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

vii. However, this warranty was false as several pregnancies have been reported subsequent to confirmation. Defendants concealed this information from Plaintiffs. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiffs. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three-month Confirmation Test was performed. Defendants concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." Women who have Essure have a 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater.[8] Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

d. "Essure is the most effective permanent birth control available – even more effective than tying your tubes or a vasectomy."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants' SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendants. Defendants stated, "We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation." Defendants concealed this information from Plaintiffs. In fact, women who have Essure have a 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[9].

e. "Correct placement…is performed easily because of the design of the micro-insert"

---

[8] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.
[9] *Id.*

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Defendants admitted that placement of the device requires a "skilled approach" and even admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendants concealed this information from Plaintiffs.

f. "Essure is a surgery-free permanent birth control."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Essure is not permanent because the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

g. "Zero pregnancies" in its clinical or pivotal trials.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "Are you Ready?" The circumstances under which Plaintiffs encountered this representation was via a brochure given to her at her implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

iv. In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

v. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an Essure advertisement. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

vi. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted reliable physicians who were approved to perform their surgery.

vii. However, this warranty was false as Defendants "signed off" on Essure physicians who did not perform the procedure every 6-8 weeks, including the implanting physicians. Defendants concealed this information from Plaintiffs.

h. You'll never have to worry about unplanned pregnancy again.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled, "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control or online.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

i. Defendants marketed with commercials stating during the procedure: "the tip of each insert remains visible to your doctor, so proper placement can be confirmed."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty

located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Essure does not allow for visual confirmation of proper placement during the procedure.

j. "Worry free"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that they did not have to worry about working or causing serious health problems.

iii. However, Defendants actively concealed and failed to report eight (8) perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued by the FDA to Defendants. Defendants actively concealed this from Plaintiffs. Defendants were issued another Form 483 when it "erroneously used non-conforming material". Defendants actively concealed this and were issued an additional Form 483 for "failing to adequately document the situation." Defendants actively concealed this from Plaintiffs. Defendants' facility was also issued a notice of violation as it "no longer uses pre-sterile and post-sterile cages". Defendants actively concealed this from Plaintiffs. Defendants also were issued a notice of violation when they "failed to obtain a valid license…prior to manufacturing medical devices". Defendants were manufacturing devices for three years without a license. Defendants actively concealed this from Plaintiffs. Defendants were also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. Defendants actively concealed this from Plaintiffs. Defendants failed to notice the FDA of their internal excel file containing

16,047 entries of complaints. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%". Defendants were issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

k. "The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled, "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that implanting physicians could confirm they were placed properly and would not migrate or cause other health problems.

iii. However, this warranty was false as the micro-inserts do not remain secure but migrate and are expelled by the body. Defendants actively concealed this information from Plaintiffs. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued to Defendants by the FDA. Defendants were issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

l. "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty

located on an advertisement entitled, "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause serious health problems.

iii. However, this warranty was false as the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiffs. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendants also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known." PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion. Most egregiously, Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and were issued another Form 483 for "failing to adequately document the situation."

m. Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants also state that it is only after "The Confirmation" test that pregnancy cannot occur, i.e., the complete opposite of what is warranted in the brochure. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was performed. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked". There have been incidents where the micro-inserts were

expelled from the body even after the Confirmation Test.[10]

n. "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure is not "surgery-free"; rather, surgery is not required. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%".

o. Essure is a …permanent birth control procedure-without … the risks of getting your tubes tied.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure does not eliminate the risks associated with other surgeries, such as tubal ligation, but actually includes more risks which were not known to Plaintiffs.

[10] *Essure insert expulsion after 3-month hysterosalpingogram,* US National Library of Medicine, Garcia, Al.

p. "The inserts are made from…safe, trusted material."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause serious health problems.

iii. However, this warranty was false as the inserts are not made of safe, trusted material as they migrate, corrode, break, and contain drugs. In fact, Defendants refer to Essure and classify it as a "drug."

q. Defendants' Essure booklet warrants: "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty in a booklet advertisement entitled "Essure: Permanent Birth Control". The circumstances under which Plaintiffs encountered this representation was via a brochure given to them at their implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause other health problems. Moreover, Plaintiffs wanted a birth control that did not irritate their uterus like other forms of birth control.

iii. However, this warranty was false because Essure does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendants concealed this information from Plaintiffs. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483. Defendants were issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and

instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

r. "there was no cutting, no pain, no scars…"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that did not cause pain, cutting or scars like other forms of birth control do.

iii. However, this warranty was false as Plaintiffs have experienced pain as a result of Essure. Defendants concealed this information from Plaintiffs. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483s for not disclosing MDRs to the FDA for pain. Defendants altered the records of at least one trial participant to reflect less pain.

427. Defendants' "affirmations of fact or promise" and "descriptions" created a basis of the bargain for Plaintiffs as noted above.

428. The warranties were specifically negotiated, directed, intended, and expressly communicated to Plaintiffs in such a manner that Plaintiffs understood and accepted them. Moreover, Plaintiffs provided reasonable notification of the breach.

429. These warranties, in effect, over-promoted Essure and nullified otherwise adequate warnings.

430. As a result of Defendants' warranties and Plaintiffs' reliance on same, Plaintiffs have suffered damages. Specifically, the Essure device did not perform as warranted and instead

migrated, perforated, broke, and/or caused other injuries noted above.

431. As a result of Defendants' breaches individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

432. As a result of Defendants' breaches, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

433. As a result of Defendants' breaches, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

434. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

435. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

D. NEGLIGENT MISREPRESENTATION – COUNT IV

436. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

437. Defendants made the following misrepresentations:

a. "Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty which was located on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiffs.

b. "There were Zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiffs.

c. "Physicians must be signed-off to perform Essure procedures"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable physician who was approved to perform the surgery.

iii. However, this warranty was false as Defendants failed to abide by the FDA guidelines when training the implanting physicians and "signed-off" on the implanting physicians who did not have the requisite training. Defendants concealed this information from Plaintiffs.

d. "Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as several pregnancies have been reported subsequent to confirmation. Defendants concealed this information from Plaintiffs. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiffs. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three-month Confirmation Test was performed. Defendants concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked". Women who have Essure have a 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater.[11] Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%".

e. "Essure is the most effective permanent birth control available – even more effective than tying your tubes or a vasectomy."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the

[11] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization*, Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.

internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants' SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendants. Defendants stated, "We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation." Defendants concealed this information from Plaintiffs. In fact, women who have Essure have a 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[12].

f. "Correct placement…is performed easily because of the design of the micro-insert."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Defendants admitted that placement of the device requires a "skilled approach" and even admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendants concealed this information from Plaintiffs.

g. "The Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on

[12] *Id.*

Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted an implanting physician that was properly trained on placing the device and managing any technical issues.

iii. However, this warranty was false as Defendants failed to train the implanting physicians pursuant to the FDA guidelines. Defendants concealed this information from Plaintiffs.

h. "Essure is a surgery-free permanent birth control."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Essure is not permanent as the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

i. "Zero pregnancies" in its clinical or pivotal trials.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "Are you Ready?" The circumstances under which Plaintiffs encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

j. In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an Essure advertisement. The circumstances under which Plaintiffs encountered this representation was via a brochure at the implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable physician who was approved to perform surgery.

iii. However, this warranty was false as Defendants "signed off" on "Essure physicians" who did not perform the procedure every 6-8 weeks, including the implanting physicians. Defendants concealed this information from Plaintiffs.

k. You'll never have to worry about unplanned pregnancy again.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

l. Defendants marketed with commercials stating during the procedure: "The tip of each insert remains visible to your doctor, so proper placement can be confirmed."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily

performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Essure does not allow for visual confirmation of proper placement during the procedure.

m. "Worry free"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that they did not have to worry about working or causing serious health problems.

iii. However, Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued by the FDA to Defendants. Defendants actively concealed this from Plaintiffs. Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and were issued an additional Form 483 for "failing to adequately document the situation." Defendants actively concealed this from Plaintiffs. Defendants' facility was also issued a notice of violation as it "no longer uses pre-sterile and post-sterile cages." Defendants actively concealed this from Plaintiffs. Defendants also were issued a notice of violation when they "failed to obtain a valid license…prior to manufacturing medical devices." Defendants were manufacturing devices for three years without a license. Defendants actively concealed this from Plaintiffs. Defendants were also issued a notice of violation as they were manufacturing medical devices at an unlicensed facility. Defendants actively concealed this from Plaintiffs. Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk

analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

n. "The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause other health problems.

iii. However, this warranty was false as the micro-inserts do not remain secure but migrate and are expelled by the body. Defendants actively concealed this information from Plaintiffs. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483 issued to Defendants by the FDA. Defendants were issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

o. "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and

saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause serious health problems.

iii. However, this warranty was false as the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiffs. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendants also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known." PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion. Most egregiously, Defendants were issued another Form 483 when they "erroneously used non-conforming material." Defendants actively concealed this and were issued another Form 483 for "failing to adequately document the situation".

p. Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants also state that it is only after "The Confirmation" that pregnancy cannot occur, i.e., the complete opposite of what is warranted in the brochure. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was confirmed. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." There have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[13].

q. "Essure eliminates the risks, discomfort, and recovery time associated

[13] *Essure insert expulsion after 3-month hysterosalpingogram,*, US National Library of Medicine, Garcia, Al.

with surgical procedures."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure is not "surgery-free", rather surgery is not required. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%".

r. "Essure is a …permanent birth control procedure – without … the risks of getting your tubes tied."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure does not eliminate the risks associated with other surgeries, such as tubal ligation, but actually includes more risks which were not known to Plaintiffs.

s. "The inserts are made from…safe, trusted material."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered

this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause serious health problems.

iii. However, this warranty was false as the inserts are not made of safe, trusted material as they migrate, corrode, break, cause injuries, and contain drugs. In fact, Defendants refer to Essure and classify it as a "drug."

t. Defendants' Essure booklet warrants: "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty in a booklet advertisement entitled "Essure: Permanent Birth Control." The circumstances under which Plaintiffs encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause other health problems. Moreover, Plaintiffs wanted a birth control that did not irritate their uterus like other forms of birth control.

iii. However, this warranty was false as Essure does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendants concealed this information from Plaintiffs. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483. Defendants were issued Form 483s for not disclosing MDRs to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis; not documenting non-conforming products; not following procedures used to control non-confirming product; and other quality problems.

u. "there was no cutting, no pain, no scars…"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty in a booklet advertisement entitled "Essure: Permanent Birth Control." The circumstances under which Plaintiffs encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that did not cause pain, cutting or scars like other forms of birth control do.

iii. However, this warranty was false as Plaintiffs experienced pain as a result of Essure. Defendants concealed this information from Plaintiffs. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483s for not disclosing MDRs to the FDA for pain. Defendants altered the records of at least one trial participant to reflect less pain.

438. Plaintiffs justifiably relied on the misrepresentations. Specifically, Plaintiffs would have never had Essure implanted had they been aware of the falsity of the representations specifically delineated in the preceding paragraphs which violate both federal law and the CPMA.

439. Moreover, these misrepresentations, in effect, over-promoted Essure and nullified otherwise adequate warnings.

440. As a result of Defendants' misrepresentations and Plaintiffs' reliance on same, Plaintiffs have suffered damages. Specifically, the Essure device did not perform as represented and instead migrated, perforated, broke and/or caused other injuries, all to Plaintiffs' damage.

441. As a result of Defendants' negligence individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

442. As a result of Defendants' negligence, individually, jointly, and severally,

Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

443. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

444. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies, along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

445. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

E. NEGLIGENCE – FAILURE TO WARN – COUNT V

446. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

447. Plaintiffs' injuries were caused by the negligent and reckless conduct of Defendants in failing to warn Plaintiffs or their implanting physicians, all of which hinge on violations of federal law and its CPMA.

448. Defendants had a duty to warn Plaintiffs and/or their implanting physicians consistent with federal law and its CMPA which included:

(a) 21 C.F.R. 814, governing premarket approval of medical devices, a *Statement of material fact* means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

(b) 21 C.F.R. 814.80 – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a condition of approval specified in the PMA approval order for the device.

(c) 21 C.F.R. 820.65 – establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.

(d) 21 C.F.R. 803.1(a) – This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified follow up. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(e) 21 C.F.R. 803.10 – (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us. (2) Submit annual reports (described in 803.33) to us. (b) If you are an importer, you must submit reports (described in subpart D of this part), as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or (ii) Submit reports of device-related malfunctions to the manufacturer. (2) [Reserved]. (c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction. (2) Submit reports of individual adverse events no later than 5 work days after the

day that you become aware of: (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or (ii) A reportable event for which we made a written request. (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

(f) 21 C.F.R. 803.50(a) – (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. (b) What information does FDA consider "reasonably known" to me? (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you: (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device. (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

(g) 21 C.F.R. 803.53 – You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than 5 work days after the day that you become aware that: (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or (b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(h) 21 C.F.R. 806.10 – (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device; or (2) To remedy a violation of the

act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b). (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal. (c) The manufacturer or importer shall include the following information in the report: (1) The seven-digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven-digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven-digit registration number will be assigned a seven digit central file number by the district office reviewing the reports. (2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal. (3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device. (4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA. (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number. (6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report. (7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken. (8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers. (9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal. (10) The date of manufacture or distribution and the device's expiration date or expected life. (11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices

distributed to each such consignee. (12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section. (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted. (d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available. (e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury. (f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter. [62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013].

(i) 21 C.F.R. 814.84 – (a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device. (b) Unless FDA specifies otherwise, any periodic report shall: (1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b). (2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA: (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant. (ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted. (3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter. (4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device

identifier discontinued prior to December 23, 2013.

(j) 21 C.F.R. 820.65 – Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

(k) 21 C.F.R. 822 – Post market surveillance – This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (FDCA) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria: (a) Failure of the device would be reasonably likely to have serious adverse health consequences; (b) The device is intended to be implanted in the human body for more than 1 year;… The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

(l) 21 C.F.R. 820.100(a) 6-7 – Corrective and Preventive Action – (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems; (2) Investigating the cause of nonconformities relating to product, processes, and the quality system; (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review. (b) All activities required under this section, and their results, shall be documented.

(m) 21 C.F.R. 820.70(e)(h) (a) *General.* Each manufacturer shall develop, conduct,

control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include: (1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production; (2) Monitoring and control of process parameters and component and device characteristics during production; (3) Compliance with specified reference standards or codes; (4) The approval of processes and process equipment; and (5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples. (b) *Production and process changes.* Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40. (e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality. (h) *Manufacturing material.* Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

(n) 21 C.F.R. 820.90 – (a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented. (b) *Nonconformity review and disposition.* (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use. (2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

(o) 21 C.F.R. 820.90 – (a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate. (b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

(p) 21 C.F.R. 820.180 – All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(q) 21 C.F.R. 820.198 – (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary. (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The

record of investigation shall include: (1) The name of the device; (2) The date the complaint was received; (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; (4) The name, address, and phone number of the complainant; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action taken; and (8) Any reply to the complainant. (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor.

(r) 21 C.F.R. 820.30 – Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(s) 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a) – A drug or device shall be deemed to be misbranded…if its labeling is false or misleading. The following acts and the causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce…any device that is adulterated or misbranded.

(t) 21 U.S.C. 351(a) (h) – A drug or device shall deemed to be adulterated…if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice…if it is…not in conformity with…an applicable condition prescribed by an order.

(u) 21 U.S.C. 352 (q) (r) – Restricted devices using false or misleading advertising or used in violation of regulations. In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title. Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a

brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

(v) FDA requirement in CPMA order – "Within 10 days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

(w) FDA requirement in CPMA order – "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(x) FDA requirement in CPMA order – Report Due Dates – six month, one year, eighteenth month, and two year reports.

(y) FDA requirement in CPMA order – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

(z) FDA requirement in CPMA order – Warranties are truthful, accurate, and not misleading…Warranties are consistent with applicable federal and state law.

449. Defendants breached these duties by not complying with the CPMA or federal law:

(a) Defendants failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteenth month and two year reports. All reports failed to meet the respective deadlines.

(b) Defendants failed to document successful placement of Essure concealing the failure rates.

(c) Defendants failed to notice the FDA of several adverse reactions and actively concealed the same. Defendants failed to report 8 perforations which occurred as a result of Essure and was cited for the same by the FDA via Form 483.

(d) Defendants failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury

concealing the injuries. Again, Defendants failed to report 8 perforations as adverse events which occurred as a result of Essure to the FDA as evidenced in Form 483.

(e) Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints.

(f) Defendants excluded the risk assessment for safety of loose coils in its Risk Management Plan and stated that Defendants had violated the FDCA.

(g) Erroneously using non-conforming material in the manufacturing of Essure.

(h) Failing to use pre-sterile and post-sterile cages.

(i) Manufacturing Essure at an unlicensed facility.

(j) Manufacturing Essure for three years without a license to do so.

(k) Not reporting … complaints in which their product migrated.

(l) Not considering these complaints in their risk analysis for the design of Essure.

(m) Failing to document CAPA activities for a supplier corrective action.

(n) On January 6, 2011, the FDA issued a violation to Defendants for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." Form 483/Violation form issued by Timothy Grome on January 6, 2011. These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes. Defendants were issued these violations for dates of incidents 5/11/10, 9/1/10, 10/1/10, 10/5/10, 10/26/10, 11/3/10, 11/5/10, and 11/16/10.

(o) Defendants had notice of 168 perforations but only disclosed 22 to the FDA.

(p) On January 6, 2011, Defendants were cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure did not include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

(q) On January 6, 2011, Defendants were cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' Design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain

detachment failures. The FDA found that Defendants' engineers learned of this and it was not documented.

(r) On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).

(s) On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

(t) Defendants failed to disclose to Plaintiffs and their implanting physicians the fact that Defendants altered medical records to reflect less pain then was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.

450. Had Defendants disclosed such information as was required by the CPMA and federal law to Plaintiffs or the Implanting Physicians, Plaintiffs would never have had Essure implanted and would have avoided their injuries.

451. At all times referenced herein, Defendants and each of them were acting as agents and employees of each of the other Defendants and were acting within the scope, purpose and authority of that agency and employment and with full knowledge, permission and consent of each other Defendant.

452. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained the injuries noted above.

453. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

454. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, both physical and mental, and will continue to

do so into the indefinite future.

455. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, and therapies, along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

456. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

F. LOSS OF CONSORTIUM – COUNT VI

457. Plaintiffs William Andamasaris, Joe Amission, Charles Helloms, Clarence Loper, Anthony Page, Jarbas DeAlmeida, Eugene Kirby, Roy Kemp, incorporate by reference each preceding and succeeding paragraph as though fully set forth at length herein.

458. As a direct and proximate cause of Defendants' conduct, as described above, Plaintiffs' wives suffered and continue to suffer from the injuries as set forth previously in this Amended Complaint.

459. Before suffering these injuries, Plaintiffs' relationships with their wives were happy and healthy.

460. As a direct and proximate result of these injuries, Plaintiffs' spouses have been unable to perform the duties of a wife. Specifically, since being implanted with Essure®,

Plaintiffs' wives are no longer able to tend to everyday household chores such as cleaning, performing yard work, driving or running errands as a result of their constant severe pain.

461. Whereas Plaintiffs' wives were once happy and energetic, this is no longer the case, as their wives now experience severe pain, depression and fatigue since being implanted with Essure®.

462. Whereas prior to undergoing the implantation of Essure®, Plaintiffs and their wives enjoyed a healthy level of sexual intimacy, after their wives were implanted with Essure® the couples' level of sexual intimacy sharply declined.

463. As a direct result of the injuries sustained by Plaintiffs' wives, they are no longer able to provide Plaintiffs with the society and services of a wife, such as intimacy, companionship, affection, assistance, and support.

464. As a direct result of the injuries from the implantation of the Essure® device, Plaintiffs wives are unable to perform the duties of a wife as they had prior to being implanted with Essure®, thereby depriving Plaintiffs of the society and services of a wife.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount according to proof at the time of trial;

2. Past and future economic and special damages according to proof at trial;

3. Loss of earnings and impaired earning capacity according to proof at trial;

4. Medical expenses, past and future, according to proof at the time of trial;

5. Equitable relief as the Court deems just and proper;

6. Declaratory judgment that Defendants are liable to Plaintiffs for all future evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendants' wrongdoing;

7. Medical monitoring, whether denominated as damages or in the form of equitable relief according to proof at the time of trial;

8. Punitive or exemplary damages according to proof at the time of trial;

9. Costs of suit incurred herein;

10. Pre-judgment interest as provided by law; and

11. Such other and further relief as the Court may deem just and proper.

Dated: June 29, 2017. By: */s/ C. Moze Cowper*

C. Moze Cowper
(NJ #00452001)
(TX #24095180)
Cowper Law
815-A Brazos Street #517
Austin, Texas 78701
Office: 877.LAW.3707
mcowper@cowperlaw.com
Attorneys for Plaintiffs

Dated: June 29, 2017. By: */s/ Joseph G. Sauder*

McCune·Wright·Arevalo, LLP
Joseph G. Sauder
PA Attorney ID #82467
Joseph B. Kenney
PA Attorney ID #316557
555 Lancaster Avenue
Berwyn, PA 19312
jgs@mccunewright.com
jbk@mccunewright.com
Local Counsel for Plaintiffs

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: June 29, 2017. By: */s/ C. Moze Cowper*

C. Moze Cowper
(NJ #00452001)
(TX #24095180)
Cowper Law
815-A Brazos Street #517
Austin, Texas 78701
Office: 877.LAW.3707
mcowper@cowperlaw.com
Attorneys for Plaintiffs

Dated: June 29, 2017.

By: */s/ Joseph G. Sauder*

McCune·Wright·Arevalo, LLP
Joseph G. Sauder
PA Attorney ID #82467
555 Lancaster Avenue
Berwyn, PA 19312
jgs@mccunewright.com
Local Counsel for Plaintiffs